

BIOVAIL CORP INTERNATIONAL
Form 20-F
May 14, 2004

[QuickLinks](#) -- Click here to rapidly navigate through this document

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 20-F

o Registration Statement Pursuant to Section 12(b) or 12(g) of The Securities Exchange Act of 1934

OR

ý Annual Report Pursuant to Section 13 or 15(d) of The Securities Exchange Act of 1934 for the fiscal year ended December 31, 2003

OR

o Transition Report Pursuant to Section 13 or 15(d) of The Securities Exchange Act of 1934 for the transition period from _____ to _____

Commission file number 001-11145

BIOVAIL CORPORATION

(Exact Name of Registrant as Specified in its Charter)

Not Applicable

(Translation of Registrant's Name into English)

Province of Ontario, Canada

(Jurisdiction of incorporation or organization)

**7150 Mississauga Road
Mississauga, Ontario
CANADA, L5N 8M5**

(Address of principal executive offices)

Securities registered or to be registered pursuant to Section 12(b) of the Act:

Title of Each Class	Name of Each Exchange on Which Registered
----------------------------	--

Common Shares, No Par Value	New York Stock Exchange Toronto Stock Exchange
-----------------------------	---

Securities registered or to be registered pursuant to Section 12(g) of the Act: NONE

Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act: NONE

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 20-F

Indicate the number of outstanding shares of each of the issuer's classes of capital or common stock as of the close of the period covered by the annual report: 158,796,978 common shares, no par value, as of December 31, 2003

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes No

Indicate by check mark which financial statement item the registrant has elected to follow.

Item 17 Item 18

TABLE OF CONTENTS

GENERAL INFORMATION

PART 1

	<u>Page</u>	
Item 1.	Identity of Directors, Senior Management and Advisors	1
	A. Directors and Senior Management	1
	B. Advisers	1
	C. Auditors	1
Item 2.	Offer Statistics and Expected Timetable	1
	A. Offer Statistics	1
	B. Method and Expected Timetable	1
Item 3.	Key Information	1
	A. Selected Consolidated Financial Data	1
	B. Capitalization and Indebtedness	3
	C. Reasons for the Offer and Use of Proceeds	3
	D. Risk Factors	3
Item 4.	Information on the Company	9
	A. History and Development of the Company	9
	B. Business Overview	9
	C. Organizational Structure	38
	D. Property, Plant and Equipment	38
Item 5.	Operating and Financial Review and Prospects	40
	A. Operating Results	40
	B. Liquidity and Capital Resources	40
	C. Research and Development, Patents and Licenses	40
	D. Trend Information	40
	E. Off-Balance Sheet Arrangements	40
	F. Tabular Disclosure of Contractual Obligations	40
	G. Safe Harbor	40
Item 6.	Directors, Senior Management and Employees	98
	A. Directors and Senior Management	98
	B. Compensation	100
	C. Board Practices	103
	D. Employees	109
	E. Share Ownership	109
Item 7.	Major Shareholders and Related Party Transactions	109
	A. Major Shareholders	109
	B. Related Party Transactions	110
	C. Interests of Experts and Counsel	110
Item 8.	Financial Information	110
	A. Consolidated Statements and Other Financial Information	110
	B. Litigation	111

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 20-F

	C. Dividend Policy	113
	D. Significant Changes	113
Item 9.	The Offer and Listing	113
	A. Nature of Trading Market	113
	B. Plan of Distribution	114
	C. Markets	114
	D. Selling Shareholders	114
	E. Dilution	114
	F. Expenses of the Issue	115
Item 10.	Additional Information	115
	A. Share Capital	115
	B. Memorandum and Articles of Association	115
	C. Material Contracts	116
	D. Exchange Controls	116
	E. Taxation	117
	F. Dividends and Paying Agents	120
	G. Statements by Experts	120
	H. Documents on Display	120
	I. Subsidiary Information	121
Item 11.	Quantitative and Qualitative Disclosures About Market Risk	121
Item 12.	Description of Securities Other Than Equity Securities	121
	A. Debt Securities	121
	B. Warrants and Rights	121
	C. Other Securities	121
	D. American Depository Shares	121

PART II

Item 13.	Defaults, Dividend Arrearages and Delinquencies	122
Item 14.	Material Modification to the Rights of Security Holders and Use of Proceeds	122
Item 15.	Controls and Procedures	122
Item 16.	[Reserved]	122
Item 16A	Audit Committee Financial Expert	122
Item 16B	Code of Ethics	122
Item 16C	Principal Accountant Fees and Services	122
Item 16D	Exemptions from the Listing Standards for Audit Committee	123
Item 16E	Purchases of Equity Securities by the Issuer and Affiliated Purchases	123

PART III

Item 17.	Financial Statements	123
Item 18.	Financial Statements	123
Item 19.	Exhibits	III-1
	Signatures	III-2
	Certifications	III-5

Basis of Presentation

Unless otherwise indicated, all references in this report to the "Company", "Biovail", "we", "us", "our" or similar terms refer to Biovail Corporation together with its subsidiaries.

All dollar amounts in this report are expressed in United States ("U.S.") dollars except where stated otherwise. In this report, unless stated otherwise, all references to "U.S.\$" or "\$" are to the lawful currency of the U.S. and all references to "C\$" are to the lawful currency of Canada.

The following words are trademarks of the Company and may be registered in Canada, the U.S. and certain other jurisdictions: Ativan®, Biovail®, Cardisense®, Cardizem®, CEFORM , DrinkUp , Fastab , FlashDose®, Glumetza , Instatab , Isordil®, Ralivia , Shearform , Smartcoat , SportSafe®, Tiazac®, Teveten®, Vasotec® and Vaseretic®.

Wellbutrin®, Wellbutrin SR®, Wellbutrin XL , Zovirax®, and Zyban® are trademarks of The GlaxoSmithKline Group of Companies and are used by the Company under license.

All other trademarks mentioned in this report, which are not the property of the Company, are owned by their respective holders and may be used under license by the Company.

Forward Looking Statements

"Safe Harbor" statement under the U.S. Private Securities Litigation Reform Act of 1995:

To the extent any statements made in this release contain information that is not historical, these statements are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. We have based these forward-looking statements on our current expectations and projections about future events. Our actual results could differ materially from those discussed in, or implied by, these forward-looking statements. Forward-looking statements are identified by words such as "believe", "anticipate", "expect", "intend", "plan", "will", "may" and other similar expressions. In addition, any statements that refer to expectations, projections or other characterizations of future events or circumstances are forward-looking statements. Forward-looking statements include, but are not necessarily limited to, risks and uncertainties, including the difficulty of predicting predicting U.S. Food and Drug Administration ("FDA") and Canadian Therapeutic Products Directorate ("TPD") approvals, acceptance and demand for new pharmaceutical products, the impact of competitive products and pricing, new product development and launch, reliance on key strategic alliances, availability of raw materials and finished products, third parties, the regulatory environment, fluctuations in operating results and other risks detailed from time to time in the Company's filings with the Securities and Exchange Commission ("SEC") and the Ontario Securities Commission ("OSC") including the risks set forth in Item 3 of this report.

PART I

Item 1. Identity of Directors, Senior Management and Advisors

- A.
Director and Senior Management
 Not applicable
- B.
Advisers
 Not applicable
- C.
Auditors
 Not applicable

Item 2. Offer Statistics and Expected Timetable

- A.
Offer Statistics
 Not applicable
- B.
Method and Expected Timetable
 Not applicable

Item 3. Key Information

A. Selected Consolidated Financial Data

Beginning January 1, 2000, we changed from publicly reporting our financial results prepared in accordance with Canadian generally accepted accounting principles ("**Canadian GAAP**") to publicly reporting those results prepared in accordance with United States generally accepted accounting principles ("**U.S. GAAP**"). The audited financial statements prepared in accordance with Canadian GAAP and U.S. GAAP are included under Item 18 "Financial Statements".

The following tables of selected consolidated financial data of the Company have been derived from financial statements prepared in accordance with U.S. GAAP and Canadian GAAP, as indicated. The data is qualified by reference to and should be read in conjunction with the consolidated financial statements and related notes thereto prepared in accordance with U.S. GAAP and Canadian GAAP.

In accordance with U.S. GAAP
 (All dollar amounts are expressed in thousands of U.S. dollars,
 except number of shares and per share data)

Years ended December 31,

	2003	2002	2001	2000	1999
Consolidated operating data:					
Revenue	\$ 823,722	\$ 788,025	\$ 583,263	\$ 309,170	\$ 172,464
Operating income (loss) ⁽¹⁾	16,936 ⁽²⁾	133,584 ⁽⁴⁾	172,228 ⁽⁵⁾	(77,796) ⁽⁷⁾	(40,218) ⁽⁹⁾
Net income (loss)	(27,265) ⁽³⁾	87,795 ⁽⁴⁾	87,448 ⁽⁶⁾	(147,976) ⁽⁸⁾	(109,978) ⁽¹⁰⁾
Basic earnings (loss) per share	\$ (0.17) ⁽³⁾	\$ 0.58 ⁽⁴⁾	\$ 0.64 ⁽⁶⁾	\$ (1.16) ⁽⁸⁾	\$ (1.07) ⁽¹⁰⁾
Diluted earnings (loss) per share	\$ (0.17) ⁽³⁾	\$ 0.55 ⁽⁴⁾	\$ 0.58 ⁽⁶⁾	\$ (1.16) ⁽⁸⁾	\$ (1.07) ⁽¹⁰⁾

As at December 31,

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 20-F

As at December 31,

	2003	2002	2001	2000	1999
Consolidated balance sheet data:					
Cash and cash equivalents	\$ 133,261	\$ 56,080	\$ 434,891	\$ 125,144	\$ 178,086
Working capital	149,884	(23,527)	427,856	(25,295)	266,068
Total assets	1,922,774	1,833,804	1,331,483	1,107,267	467,179
Long-term obligations	822,927	747,350	46,161	438,744	137,504
Convertible Subordinated Preferred Equivalent Debentures				299,985	
Shareholders' equity	\$ 881,595	\$ 845,686	\$ 1,126,074	\$ 237,458	\$ 267,336
Number of common shares issued and outstanding [000s]	158,797	158,120	157,496	131,461	124,392

- (1) Current and prior years' figures reflect the reclassification of foreign exchange gains and losses from selling, general and administrative expenses.
- (2) Including charges of \$7,539 for relocation costs, \$45,081 relating to the write-down of certain assets, \$124,720 for acquired research and development, and \$61,348 for the extinguishment of a royalty obligation.

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 20-F

- (3) Including charges of \$7,539 for relocation costs, \$45,081 relating to the write-down of certain assets, \$124,720 for acquired research and development, \$61,348 for the extinguishment of a royalty obligation, \$13,061 for a foreign exchange loss on a long-term obligation, and a reduction in the provision for tax contingencies of \$12,000.
- (4) Including charges of \$31,944 relating to the write-down of certain assets and \$167,745 for acquired research and development.
- (5) Including a charge of \$80,482 relating to the write-down of certain assets.
- (6) Including charges of \$80,482 relating to the write-down of certain assets and \$34,923 for the debt conversion premiums relating to the conversion of our 6.75% Convertible Subordinated Preferred Equivalent Debentures due 2025 ("**Debentures**").
- (7) Including a charge of \$208,424 for acquired research and development.
- (8) Including charges of \$208,424 for acquired research and development, \$20,039 for a premium paid on the early extinguishment of the 10⁷/₈% U.S. Dollar Senior Notes due 2005 ("**Senior Notes**"), and \$43,500 (\$0.34 basic and diluted loss per share) for the cumulative effect of a change in accounting principle relating to the recognition of revenue.
- (9) Including a charge of \$105,689 for acquired research and development.
- (10) Including charges of \$105,689 for acquired research and development and \$58,399 in respect of the equity loss in Fuisz Technologies Ltd. ("**Fuisz**"), and a net gain of \$1,948 on disposal of certain long-term investments.

In accordance with Canadian GAAP
(All dollar amounts are expressed in thousands of U.S. dollars,
except number of shares and per share data)

Years ended December 31,

	2003	2002	2001	2000	1999
Consolidated operating data:					
Revenue	\$ 823,722	\$ 788,025	\$ 583,263	\$ 311,457	\$ 165,092
Operating income (loss) ⁽¹⁾	4,793 ⁽²⁾	246,979 ⁽⁴⁾	117,382 ⁽⁵⁾	116,459	64,059
Net income (loss) attributable to common shareholders	(40,345) ⁽³⁾	207,553 ⁽⁴⁾	85,553 ⁽⁶⁾	81,163 ⁽⁷⁾	51,080 ⁽⁸⁾
Basic earnings (loss) per share	\$ (0.25) ⁽³⁾	\$ 1.37 ⁽⁴⁾	\$ 0.62 ⁽⁶⁾	\$ 0.63 ⁽⁷⁾	\$ 0.50 ⁽⁸⁾
Diluted earnings (loss) per share	\$ (0.25) ⁽³⁾	\$ 1.29 ⁽⁴⁾	\$ 0.57 ⁽⁶⁾	\$ 0.57 ⁽⁷⁾	\$ 0.47 ⁽⁸⁾
As at December 31,					
	2003	2002	2001	2000	1999
Consolidated balance sheet data:					
Cash and cash equivalents	\$ 133,261	\$ 56,080	\$ 434,891	\$ 125,144	\$ 178,086
Working capital	149,884	(23,527)	427,856	(25,295)	256,768
Total assets	2,297,604	2,237,666	1,643,026	1,460,967	635,137
Long-term obligations	812,526	732,111	46,161	438,744	137,504
Shareholders' equity	\$ 1,266,826	\$ 1,264,787	\$ 1,425,417	\$ 839,110	\$ 391,794
Number of common shares issued and outstanding [000s] ⁽⁹⁾	158,797	158,120	157,496	131,461	124,392

(1) Current and prior years' figures reflect the reclassification of foreign exchange gains and losses from selling, general and administrative expenses.

(2)

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 20-F

Including charges of \$7,539 for relocation costs, \$82,189 relating to the write-down of certain assets, and \$61,348 for the extinguishment of a royalty obligation.

- (3) Including charges of \$7,539 for relocation costs, \$82,189 relating to the write-down of certain assets, \$61,348 for the extinguishment of a royalty obligation, \$13,061 for a foreign exchange loss on a long-term obligation, and a reduction in the provision for tax contingencies of \$12,000.
- (4) Including a charge of \$31,944 relating to the write-down of certain assets.
- (5) Including a charge of \$80,482 relating to the write-down of certain assets.
- (6) Including charges of \$48,246, net of tax of \$32,236, relating to the write-down of certain assets and \$10,001 for the debt conversion premiums relating to the conversion of the Convertible Subordinated Preferred Equivalent Debentures.
- (7) Including a charge \$20,039 for a premium paid on the early extinguishment of the 10⁷/₈% U.S. Dollar Senior Notes due 2005 ("Senior Notes")

- (8) Including a charge of \$1,618 in respect of the equity loss in Fuisz Technologies Ltd., and a net gain of \$1,948 on disposal of certain long-term investments.
- (9) All share amounts have been adjusted to give effect to the 2 for 1 stock splits completed in December 1999 and October 2000.

B. Capitalization and Indebtedness

Not applicable

C. Reasons for the Offer and Use of Proceeds

Not applicable

D. Risk Factors

The pharmaceutical industry is highly competitive and is subject to rapid and significant technological change, which could render our technologies and products obsolete or uncompetitive.

Our products face competition from conventional forms of drug delivery and from controlled-release drug delivery systems developed, or under development, by other pharmaceutical companies. We compete with companies in North America and internationally, including major pharmaceutical and chemical companies, specialized contract research organizations, research and development firms, universities and other research institutions. Some of our competitors are also licensees or licensors of our products. Many of our competitors have greater financial resources and selling and marketing capabilities, have greater experience in clinical testing and human clinical trials of pharmaceutical products and have greater experience in obtaining FDA, TPD and other regulatory approvals. Our competitors may succeed in developing technologies and products that are more effective or less expensive to use than any that we may develop or license. These developments could render our technologies and products obsolete or uncompetitive, which would have a material adverse effect on our business and financial results.

Patent protection is unpredictable and uncertainty can arise regarding the applicability of our patents and proprietary technology.

Our competitors may have filed patent applications, or hold issued patents, relating to products or processes competitive with those we are developing or our patent applications for a product or process may not be approved or may not be approved as desired. The patents of our competitors may impair our ability to do business in a particular area or others may independently develop similar products or duplicate any of our unpatented products. Our success will depend, in part, on our ability in the future to obtain patents, protect trade secrets and other proprietary information and operate without infringing on the proprietary rights of others.

We rely on trade secrets, know-how and other proprietary information as well as requiring our employees and other vendors and suppliers to sign confidentiality agreements. However, these confidentiality agreements may be breached, and we may not have adequate remedies for such breaches. Others may independently develop substantially equivalent proprietary information without infringing upon any proprietary technology. Third parties may otherwise gain access to our proprietary information and adopt it in a competitive manner.

With respect to the segment of our business where we manufacture and supply bioequivalent versions of existing drugs, there has been substantial litigation in the pharmaceutical industry concerning the manufacture, use and sale of new products that are the subject of conflicting patent rights. When we file an Abbreviated New Drug Application ("ANDA") for a bioequivalent version of a drug, we are required to certify to the FDA that any patent which has been listed with the FDA as covering the branded product has expired, and the date any such patent will expire, or that any such patent is invalid or will not be infringed by the manufacture, sale or use of the new drug for which the application is submitted. Approval of an ANDA is not effective until each listed patent expires, unless the applicant certifies that the patents at issue are not infringed or are invalid and so notifies the patent holder and the holder of the branded product New Drug Application ("NDA"). A patent holder may challenge a notice of non-infringement or invalidity by suing for patent infringement within 45 days of receiving notice. Such a challenge would prevent FDA approval for a period, which ends 30 months after the

receipt of notice, or sooner if an appropriate court rules that the patent is invalid or not infringed. From time to time, in the ordinary course of business, we face such challenges.

The expense of litigation, whether or not we are successful, could have a material adverse effect on our business, results of operations, financial condition and cash flows. Regardless of FDA approval, should anyone commence a lawsuit with respect to any alleged patent infringement by us, whether because of the filing of an ANDA or otherwise, the uncertainties inherent in patent litigation make the outcome of such litigation difficult to predict. Such lawsuits may be brought and the ultimate outcome of such litigation, if commenced, could have a material adverse effect on our business, results of operations, financial condition and cash flows.

The publication of negative results of studies or clinical trials may adversely impact our products.

From time to time, studies or clinical trials on various aspects of pharmaceutical products are conducted by academics or others, including government agencies. The results of these studies or trials, when published, may have a dramatic effect on the market for the pharmaceutical product that is the subject of the study. The publication of negative results of studies or clinical trials related to our products or the therapeutic areas in which our products compete could adversely affect our sales, the prescription trends for our products and the reputation of our products. In the event of the publication of negative results of studies or clinical trials related to our products or the therapeutic areas in which our products compete, our business, financial condition, results of operation and cash flows could be materially adversely affected.

Future inability to obtain components and raw materials or products could affect our operations.

Some components and materials used in our manufactured products, and some products sold by us, are currently available only from one or a limited number of domestic or foreign suppliers. In the event an existing supplier becomes unavailable or loses its regulatory status as an approved source, we will attempt to locate a qualified alternative; however, we may be unable to obtain the required components, raw materials or products on a timely basis or at commercially reasonable prices. To the extent such difficulties cannot be resolved within a reasonable time, and at a reasonable cost, or we are required to qualify a new supplier, our business, financial condition, results of operation and cash flows could be materially adversely affected.

Our arrangements with foreign suppliers are subject to certain additional risks, including the availability of government clearances, export duties, political instability, currency fluctuations and restrictions on the transfer of funds. Arrangements with international raw material suppliers are subject to, among other things, FDA and TPD regulation, various import duties and required government clearances. Acts of governments outside the U.S. and Canada may affect the price or availability of raw materials needed for the development or manufacture of our products.

Our business could suffer as a result of manufacturing issues.

The continued increase in the number of products we market and have pending at the FDA and TPD requires us to continue to expand our manufacturing capabilities, including making changes to our manufacturing facilities in Puerto Rico and Steinbach, Manitoba. The timely completion of these efforts is necessary for us to have sufficient manufacturing capacity for the anticipated quantities of our existing products and the products we expect to market or out-license in the future, and will require significant levels of capital investment. Our inability to complete our expansion and conversion projects, or adequately equip the facilities in a timely manner, or delays in receiving FDA and TPD approval could adversely affect our results of operations, financial condition and cash flows.

Our manufacturing and other processes utilize sophisticated equipment, which sometimes requires a significant amount of time to obtain and install. Although we endeavor to properly maintain our equipment and have key spare parts on hand, our business could suffer if certain manufacturing or other equipment, or a portion of, our facilities were to become inoperable for period of time. This could occur for various reasons, including catastrophic events such as hurricane or explosion, but also equipment failures and/or delays in obtaining components or replacements thereof, as well as equipment issues, construction delays or defects and other events, both within and outside of our control.

We have at times operated some of our manufacturing facilities on a 24-hour a day, 7-day a week production cycle in order to meet the market demand for current and anticipated products. Operating on that basis and meeting the anticipated market demand requires minimal equipment failures and product rejections. However, because we manufacture products that employ a variety of technology platforms, some of our manufacturing capabilities may at times be over-utilized, while others may be under-utilized, resulting in inefficiencies, equipment failures and rejection of lots. Until our manufacturing processes are optimized, and our manufacturing facilities are expanded, we may have difficulty at times fulfilling all of the market demand for our existing and future products, which could adversely affect our results of operations, financial condition and cash flows. A portion of our pharmaceutical manufacturing capacity as well as other critical business functions are located in areas subject to hurricane and earthquake casualty risks. Although we have certain limited protection afforded by insurance, our business and our earnings could be materially adversely affected in the event of a major windstorm or earthquake.

Our manufacturing facilities are located outside the continental U.S. while most of our sales are within the U.S. Border controls may have an impact on our ease of access to the U.S. market place.

Our operations could be disrupted if our information systems fail or if we are unsuccessful in implementing necessary upgrades.

Our business depends on the efficient and uninterrupted operation of our computer and communications software and hardware systems and our other information technology. If our systems were to fail or we were unable to successfully expand the capacity of these systems or to integrate new technologies into our existing systems, our operations and financial results could suffer.

There is no assurance that we will continue to be successful in our licensing and marketing operations.

Certain of our products are marketed by third parties by way of license agreements or otherwise. Such third-party arrangements may not be successfully negotiated in the future. Any such arrangements may not be available on commercially reasonable terms. Even if acceptable and timely marketing arrangements are available, the products we develop may not be accepted in the marketplace, and even if such products are initially accepted, sales may thereafter decline. Additionally, our clients or marketing partners may make important marketing and other commercialization decisions with respect to products we develop without our input. As a result, many of the variables that may affect our revenues, cash flows and net income are not exclusively within our control.

The success of the strategic investments we make depends upon the performance of the companies in which we invest.

Economic, governmental, industry and internal company factors outside our control affect each of the companies in which we may invest. Some of the material risks relating to the companies in which we may invest include:

the ability of these companies to successfully develop, manufacture and obtain necessary governmental approvals for the products which serve as the basis for our investments;

the ability of competitors to develop similar or more effective products, making the drugs developed by the companies in which we invest difficult or impossible to market;

the ability of the companies in which we invest to adequately secure patents for their products and protect their proprietary information;

the ability of these companies to enter the marketplace without infringing upon competitors' patents; and

the ability of these companies to remain technologically competitive, and the dependence of these companies upon key scientific and managerial personnel.

We may have limited or no control over the resources that any company in which we invest may devote to developing the products for which we collaborate with them. Any company in which we invest may not perform as expected. These companies may breach or terminate their agreements with us or otherwise fail to conduct product discovery and development activities successfully or in a timely manner. If any of these events occurs, it could have a material adverse effect on our business.

We must successfully integrate any businesses or products that we have acquired or will acquire in the future.

We may pursue product or business acquisitions that could complement or expand our business. However, there can be no assurance that we will be able to identify appropriate acquisition candidates in the future. If an acquisition candidate is identified, there can be no assurance that we will be able to successfully negotiate the terms of any such acquisition, finance such acquisition or integrate such acquired product or business into our existing products and business. Furthermore, the negotiation of potential acquisitions and integration of acquired companies and product lines could divert management's time and resources, and require significant resources to consummate. If we consummate one or more significant acquisitions through the issuance of common shares, holders of our common shares could suffer significant dilution of their ownership interests.

We depend on key scientific and managerial personnel for our continued success.

Much of our success to date has resulted from the particular scientific and management skills of personnel available to us. If these individuals were not available, we might not be able to attract or retain employees with similar skills. In particular, our success to date in developing new products has resulted from the activities of a core group of research scientists. The continued availability of such a group is important to our ongoing success.

A relatively small group of products and customers may represent a significant portion of our net revenues or net earnings from time to time. If the volume or pricing of any of these products declines or we lose customers, it could have a material adverse effect on our business, financial condition, cash flows and results of operations.

Sales of a limited number of our products often represent a significant portion of our net revenues or net earnings. If the volume or pricing of our largest selling products declines in the future, our business, financial condition, cash flows and results of operations could be materially adversely affected.

A significant portion of our net revenues are derived from sales to a limited number of customers. Any significant reduction or loss of business with one or several of these customers could have a material adverse effect on our business, financial condition, cash flows and results of operations.

Our ability to obtain third-party reimbursement for the cost of products and related treatment may not be adequate.

Our ability to successfully commercialize our products and product candidates, even if FDA or TPD approval is obtained, depends in part on whether appropriate reimbursement levels for the cost of the products and related treatments are obtained from government authorities and private health insurers and other organizations, such as Health Maintenance Organizations ("HMOs") and Managed Care Organizations ("MCOs") and Provincial Formularies.

Third-party payors increasingly challenge the pricing of pharmaceutical products. In addition, the trend toward managed health care in the U.S., the growth of organizations such as HMOs and MCOs and legislative proposals to reform health care and government insurance programs could significantly influence the purchase of pharmaceutical products, resulting in lower prices and a reduction in product demand. Such cost containment measures and health care reform could affect our ability to sell our products and may have a material adverse effect on our business, results of operations, cash flows and financial condition.

Uncertainty exists about the reimbursement status of newly approved pharmaceutical products. Reimbursement in the U.S., Canada or foreign countries may not be available for some of our products. Any reimbursement granted may not be maintained or limits on reimbursement available from third-party payors may reduce the demand for, or negatively affect the price of, those products. These issues could have a material adverse effect on our business, results of operations and financial condition. We are unable to predict if additional legislation or regulation impacting the health care industry or third-party coverage and reimbursement may be enacted in the future, or what effect such legislation or regulation would have on our business.

Our business is subject to limitations imposed by government regulations.

Government agencies in the U.S., Canada and other countries in which we carry on business regulate pharmaceutical products intended for human use. Regulations require extensive clinical trials and other testing and government review and final approval before we can market these products. The cost of complying with government regulation can be substantial. Governmental authorities in the U.S. and Canada and comparable authorities in foreign countries regulate the research and development, manufacture, testing and safety of pharmaceutical products. The regulations applicable to our existing and future products may change. There can be long delays in obtaining required clearances from regulatory authorities in any country after applications are filed.

Requirements for approval vary widely from country to country outside of the U.S. and Canada. Whether or not approved in the U.S. or Canada, regulatory authorities in other countries must approve a product prior to the commencement of marketing the product in those countries. The time required to obtain any such approval may be longer or shorter than in the U.S. or Canada.

Any failure or delay in obtaining regulatory approvals could adversely affect the marketing of any products we develop and therefore our business, results of operations, financial condition and cash flows.

New legislation or regulatory proposals may adversely affect our revenues and profitability.

A number of legislative and regulatory proposals aimed at changing the health care system, including the cost of prescription products, importation and reimportation of prescription products from countries outside the U.S. and changes in the levels at which pharmaceutical companies are reimbursed for sales of their products, have been proposed. While we cannot predict when or whether any of these proposals will be adopted or the effect these proposals may have on our business, the pending nature of these proposals, as well as the adoption of any proposal, may exacerbate industry-wide pricing pressures and could have a material adverse effect on our business, financial condition, results of operations and cash flows.

Changes in the Medicare, Medicaid or similar governmental programs or the amounts paid by those programs for our services may adversely affect our earnings. These programs are highly regulated and subject to frequent and substantial changes and cost containment measures. In recent years, changes in these programs have limited and reduced reimbursement to providers. *The Medicare Prescription Drug, Improvement and Modernization Act of 2003*, creates a new, voluntary prescription drug benefit under the Social Security Act, which we refer to as "Medicare Drug Benefit." Beginning in 2006, Medicare beneficiaries entitled to Part A or enrolled in Part B, as well as certain other Medicare enrollees, will be eligible for the Medicare Drug Benefit. Regulations implementing the Medicare Drug Benefit have not yet been published, and the Medicare Drug Act requires that the Federal Trade Commission ("FTC") conduct a study and make recommendations regarding additional legislation that may be needed concerning the Medicare Drug Benefit. We are unable at this time to predict or estimate the financial impact of this new legislation.

Recently enacted and proposed changes in the laws and regulations affecting public companies, including the provisions of the Sarbanes-Oxley Act of 2002 in the U.S. and Bill 198 in Ontario and related rules, will cause us to incur increased costs as we evaluate the implications of new rules and respond to new requirements. Failure to comply with the new rules and regulations could result in enforcement actions or the assessment of other penalties. The new laws and regulations could make it more difficult for us to obtain certain types of insurance, including director's and officer's liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these events could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, or as executive officers. We may be required to hire additional personnel and utilize additional outside legal, accounting and advisory services, all of which could cause our general and administrative costs to increase beyond what we currently have planned. We are presently evaluating and monitoring developments with respect to these rules, and we cannot predict or estimate the amount of the additional costs we may incur or the timing of such costs.

Rising insurance costs could negatively impact our profitability.

The cost of insurance, including director and officer, worker's compensation, property, product liability and general liability insurance, have risen significantly in the past year and are expected to continue to increase in 2004. In response, we may increase deductibles and/or decrease certain coverages to mitigate these costs. These increases, and our increased risk due to increased deductibles and reduced coverages, could have a negative impact on our results of operations, financial condition and cash flows.

If we fail to comply with the "safe harbors" provided under various federal, provincial and state laws, our business could be adversely affected.

We are subject to various federal and state laws pertaining to health care "fraud and abuse," including anti-kickback laws and false claims laws. Anti-kickback laws make it illegal for a prescription drug manufacturer to solicit, offer, receive, or pay any remuneration in exchange for, or to include, the referral of business, including the purchase or prescription of a particular drug. The U.S. federal government has published regulations that identify "safe harbors" or exemptions for certain payment arrangements that do not violate the anti-kickback statutes. We seek to comply with the safe harbors. Due to the breadth of the statutory provisions and the absence of guidance in the form of regulations or court decisions addressing some of our practices, it is possible that our practices might be challenged under anti-kickback or similar laws. Our activities relating to the sale and marketing of one of our products in the U.S. are subject to the review by the Office of Inspector General's investigation.

Violations of fraud and abuse of securities laws may be punishable by civil and/or criminal sanctions, including fines and civil monetary penalties, as well as the possibility of exclusion from federal health care programs (including Medicaid and Medicare). Any such violations could have a material adverse effect on our business, financial condition, results of operations and cash flows.

Our securities are subject to market price volatility.

Market prices for the securities of pharmaceutical and biotechnology companies, including our own, have historically been highly volatile, and the market has from time to time experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies. Factors such as fluctuations in our operating results, concern as to the safety of drugs, and general market conditions can have an adverse effect on the market price of our securities.

Our effective tax rate may increase

We have operations in various countries that have differing tax laws and rates. Our income tax reporting is subject to review by both domestic and foreign tax authorities. The effective tax rate may change from year to year based on the mix of income among the different jurisdictions in which we operate, changes in tax laws in these jurisdictions, changes in the tax treaties between various countries in which we operate, and changes in the estimated values of deferred tax assets and liabilities.

We have recorded a valuation allowance on deferred tax assets primarily relating to operating losses, future tax depreciation and tax credit carryforwards. We have assumed that these deferred tax assets are more likely than not to remain unrealized. Significant judgment is applied to determine the appropriate amount of valuation allowance to record. Changes in the amount of the valuation allowance required could materially increase or decrease the provision for income taxes in a period.

Our future effective tax rate will depend on the relative profitability of our domestic and foreign operations, the statutory tax rates of the related tax jurisdictions, and the timing of the release, if any, of the valuation allowance.

We are not assured of successful development of our product pipeline.

We have over 30 products at various stages of development or which are not yet marketed. We have filed several products for approval with the FDA. Approval may not be granted for all or any of these products and we may not be successful in filing NDAs or ANDAs for the remaining pipeline products with the FDA.

We could be subject to fines, penalties, or other sanctions as a result of pending inquiries by the SEC and the OSC.

On November 20, 2003, we received a letter from the SEC indicating that the Commission will be conducting an informal inquiry relating to the Company's financial performance and certain accounting matters for the fiscal year 2003. In addition, the Company has been advised that the OSC is conducting an investigation, which it understands relates to trading of our securities prior to the issuance of press releases on October 3, 2003, which provided revised guidance for the 2003, third quarter, and October 30, 2003, which reported the financial results for the 2003, third quarter. We are providing the OSC our full cooperation. We have also received requests for information from the OSC as part of the OSC's continuous disclosure review of certain public companies in Ontario. We are responding and providing all requested information to the OSC.

Although we are cooperating with these pending inquiries, we are unable at this point to predict the scope or outcome of these inquiries, and it is possible that one or more of them could result in the institution of administrative, civil injunctive or criminal proceedings, the imposition of fines and penalties, and/or other remedies and sanctions. The conduct of these proceedings could negatively impact our stock price. In addition, we expect to continue to incur expenses associated with responding to these agencies, regardless of the outcome, and this may divert the efforts and attention of our management team from normal business operations.

Item 4. Information on the Company

A. History and Development of the Company

Biovail Corporation ("**Biovail**" or the "**Company**") is incorporated under the *Business Corporations Act* (Ontario) R.S.O. 1990, as amended. Established on March 29, 1994 as a result of the amalgamation of Trimel Corporation ("**Trimel**") and its then subsidiary, Biovail Corporation International ("**BCI**"), On February 18, 2000, we changed our name from Biovail Corporation International to Biovail Corporation.

Our principal executive office is located at 7150 Mississauga Road, Mississauga, Ontario, Canada, L5N 8M5, telephone (905) 286-3000. Our agent for service in the U.S. is CT Corporation System, located at 111 Eighth Avenue, New York, New York, 10219, telephone number (212) 590-9200.

A description of our principal capital expenditures and divestitures and a description of acquisitions of material assets is found in our Management's Discussion and Analysis ("MD&A") and consolidated financial statements included elsewhere in this annual report.

B. Business Overview

We are a fully-integrated pharmaceutical company engaged in the development, manufacture, marketing, licensing, and distribution of pharmaceutical products for the treatment of chronic medical conditions primarily in North America. Our primary focus is on the following therapeutic areas: cardiovascular disease, central nervous system (CNS) disorders and pain management. Other areas of interest include Type II diabetes, antiviral medicine and select niche therapeutic categories with identified potential. A key element of our business is the development, manufacture and sale of branded pharmaceutical products that incorporate our advanced, proprietary drug delivery technologies that provide significant therapeutic advantages over existing formulations.

We generate revenues primarily from the sale of these products, which may be marketed directly by our own sales and marketing divisions in the U.S. and Canada or through manufacturing, supply and license agreements with third party pharmaceutical companies in the U.S. and world markets. We also generate revenue by promoting and/or co-promoting products on behalf of third parties, providing research development and clinical contract research services to third parties, and through royalties and/or licensing fees related to the sale of a number of our controlled-release products by third parties.

In 2003, Biovail implemented a number of strategic initiatives aimed at enhancing our U.S. selling and marketing infrastructure and maximizing the potential of both our commercial products and our product development pipeline in the world's largest pharmaceutical market. We relocated our U.S. corporate headquarters from Raleigh, North Carolina to Bridgewater, New Jersey a recognized hub of the

pharmaceutical industry. We also reconstituted the senior management team at our U.S. operations with accomplished pharmaceutical industry executives. Among other initiatives, the new leadership team has realigned and optimized our U.S. primary care sales force, and created two specialty sales forces – one focusing on cardiovascular and nephrology specialists, the other on dermatologists and obstetricians/gynecologists ("Ob-Gyn"). While this investment in our U.S. infrastructure has impacted our financial performance in the short term, we believe these steps will facilitate the realization of the full potential of our promoted products.

We continually explore product, company and technology acquisition opportunities in the marketplace. In the past, our acquisition strategy looked to capitalize on opportunities in the global pharmaceutical industry, including those arising from consolidation or divestitures. At times, we investigate and pursue acquisitions or investment opportunities that will add to our product portfolio or pipeline, will enhance our drug delivery technology base, or will strategically expand our sales and marketing capability in our target therapeutic areas. However, in 2004, we have opted to focus our growth efforts on two fronts: (1) increasing market penetration of our promoted products and (2) the out-licensing of select pipeline products, including Ralivia ER, Ralivia FlashDose® and Glumetza, among others. Our U.S. sales force is deployed promoting Cardizem® LA, Teveten®, Teveten® HCT, Zovirax® Ointment and Zovirax® Cream, and therefore, we believe out-licensing pipeline products in the near to mid-term will maximize the market potential of the pipeline products. Longer term, and consistent with our long-term strategy of full integration, we expect to commercialize the majority of our pipeline products through our own sales force. In the interim, we believe the operational flexibility afforded by this two-pronged marketing approach will allow us to maximize our revenue and cash flow opportunities. (For further discussion of our acquisitions, see MD&A of Financial Condition and Results of Operations, contained in Item 5 of this report.)

Our Markets

Our primary market is the U.S., the world's largest pharmaceutical market with total prescription spending of \$216 billion in 2003, an 11.5% increase relative to 2002. Within that broader market, our therapeutic focus areas are cardiovascular disease (including Type II diabetes), central nervous system (CNS) disorders and pain management. We also maintain the flexibility to exploit niche markets, as we have done with our Zovirax® franchise in the treatment of herpes.

Our current portfolio of commercial products is heavily weighted to cardiovascular products, including those for the treatment of hypertension, angina, congestive heart failure and acute myocardial infarction. According to IMS Healthcare ("IMS"), the U.S. market for cardiovascular products was valued at \$24.6 billion in 2003, of which \$14.9 billion was represented by antihypertensives. Our current commercial portfolio of cardiovascular therapeutic products in the U.S. includes Cardizem® LA, Cardizem® CD, Tiazac®, Vasotec®, Vaseretic®, Teveten®, Teveten® HCT, Isordil®, and a number of generic pharmaceutical products.

CNS disorders represent another of our therapeutic focus areas. According to IMS, the U.S. market for the treatment of CNS was valued at \$14.5 billion in 2003, with the vast majority – \$13.6 billion – represented by antidepressants. Our commercial portfolio in these markets, includes Wellbutrin XL (licensed to GlaxoSmithKline plc ("GSK")), and Ativan®.

We currently have several pipeline products either being reviewed by the FDA or TPD or in late-stage development targeting pain management and Type II diabetes. Although we do not yet have any commercial products for pain management or Type II diabetes, we are committed to these markets and are building emerging franchises therein. According to IMS, the U.S. markets for these indications were valued at \$14.3 billion and \$5.5 billion, respectively, in 2003. We currently expect the commercialization of our first products in these markets in 2005.

We also have a presence in the U.S. herpes market – valued at \$1.1 billion in 2003 – through our acquisition of Zovirax® Ointment and recently launched Zovirax® Cream from GSK in October 2001. In addition, our pipeline includes an oral controlled-release formulation of acyclovir, the active ingredient in our Zovirax® products. Oral therapeutic products for herpes represent the vast majority of the overall herpes market, with 2003 sales of \$898 million. During 2003, the antiviral Zovirax® line of products was our leading revenue generator, accounting for approximately 19% of our total U.S. product revenue.

In the U.S., our products are marketed either directly by Biovail Pharmaceuticals Inc. ("BPI"), our U.S. sales and marketing organization, or through strategic licensing partners. During 2003, our U.S. sales force consisted of approximately 550 proprietary sales representatives and 250 sales representatives provided by Reliant Pharmaceuticals, LLC ("Reliant") through a strategic co-promotion agreement that was terminated effective December 31, 2003, (see Chronology of Strategic Events). In 2004, following the realignment and optimization of our U.S. sales and marketing infrastructure, our primary care sales force of 475 representatives will detail Cardizem® LA, Teveten®, Teveten® HCT, Zovirax® Ointment and Zovirax® Cream to physicians across the U.S. In addition, we have established two specialty sales forces of 63 representatives each; one of which will promote Cardizem® LA and the Teveten® line to cardiovascular and nephrology specialists, the other detailing our Zovirax® franchise to dermatologists and Ob-Gyn.

Some of our products are also marketed directly in Canada through Biovail Pharmaceuticals Canada ("BPC"), our Canadian sales and marketing division. The Canadian pharmaceutical market was valued by IMS at \$10.4 billion in 2003. Similar to our U.S. strategy, BPC's therapeutic focus lies in cardiovascular disease and CNS disorders, markets valued at \$2.4 billion and \$0.7 billion, respectively. Within these markets, our current commercial portfolio is skewed towards antihypertensives (a market valued at \$1.3 billion in 2003) and antidepressants (\$630 million). BPC's sales force consists of 78 representatives, which currently target 10,000 physicians across the country. During 2003, the anti-hypertensive/anti-angina medication Tiazac® was BPC's leading product, representing approximately 43% of total Canadian product revenues.

We also have a significant presence in generic pharmaceuticals, an industry valued by IMS at \$37 billion in 2003 a 20% increase relative to 2002. Our focus in this segment has been on the development of controlled-release generic formulations of branded products, where the competitiveness and price discounting is significantly less than in the immediate release generic market. Our generic pharmaceuticals with the exception of Tiazac®, which is licensed to Forest Laboratories Inc. ("Forest"), are distributed in the U.S. by Teva Pharmaceuticals U.S.A Inc. ("Teva") pursuant to a 1997 agreement. Although generic products no longer represent a core focus for us, we do have several products under review by the FDA, and will look to out-license these upon approval.

While our business focus is on the U.S. and Canadian markets, several of our products have been commercialized globally through licensing agreements with strategic marketing partners with expertise in their local markets.

Our Technologies

We have developed and acquired a number of advanced drug delivery technologies, which we use to create pharmaceutical products with distinct clinical and competitive advantages. Through the application of these technologies we develop products that: (1) improve upon existing multiple daily dose immediate-release products by providing the therapeutic and compliance/convenience benefits of once-daily dosing; and/or (2) are enhanced versions of existing medications that offer superior efficacy, reduced side effects and other potential benefits. Our technology portfolio includes taste-masking, orally-disintegrating (FlashDose®), controlled-release, graded-release and oral colonic drug delivery technologies.

Business Strategy

Our business strategy revolves around three inter-related components.

The first is our ability to efficiently and expeditiously exploit our pipeline products by commercialization either through our own sales force in the U.S. and Canada or through strategic out-licensing to marketing partners. This ability to access these two options appropriately to optimize the market opportunities offered by a new product provides Biovail with a degree of operational flexibility and effectively differentiates us from our competitors. The decision to market a new product directly or through marketing partnerships is based on the evaluation of a number of factors including target therapeutic market / physician population, commercialization timelines and infrastructure investment requirements.

One of our core long-term objectives is to optimize the revenue opportunities represented by our expanding branded product portfolio through our own sales operations. Our strategy is to leverage and expand our sales

and marketing presence in the U.S. and Canada to maximize sales of our existing products and to support the mid to long-term commercialization of new products from our development pipeline, as well as established in-market products that we may acquire. In 2004, given the recent infrastructure changes at BPI including the realignment and optimization of our primary care sales force, and the creation of two specialty sales forces, our U.S. sales team will be deployed detailing Cardizem® LA, Teveten®, Teveten® HCT, Zovirax® Ointment and Zovirax® Cream to U.S. physicians. Accordingly, over the near-term, we anticipate out-licensing up to half of our product pipeline, where we believe revenue opportunities can be maximized by others. Products in this category include Ralivia ER , Ralivia FlashDose® and Glumetza .

The second component of our business strategy is the strength of our drug delivery technology, evidenced by the heritage of our company and our pipeline of products under development.

We currently develop products utilizing several distinct proprietary drug delivery technology platforms, including: (1) controlled-release technologies; (2) FlashDose® or orally disintegrating tablet technology ("ODT"); (3) enhanced absorption/super bioavailable and (4) oral colonic drug delivery. Our pipeline consists of a growing number of products at various stages of development. These represent a combination of products developed by Biovail, products being developed by companies in which we have made a strategic investment, products provided by our development partners and high-promise products in various stages of development acquired under license from third parties. Our pipeline development program is complemented by the efforts of our business development group whose mandate is to expand our product pipeline by identifying New Chemical Entities (NCEs), New Biological Entities (NBEs), existing promotion-sensitive in-market brands, and novel drug delivery technologies for future commercialization in North America through our fully-integrated sales and marketing organization or through out-licensing.

Our focus on the cardiovascular (including Type II diabetes), CNS and pain management therapeutic areas allows us to channel our expertise and to concentrate our activities in those areas where we perceive the highest growth potential. While we will prudently continue to explore development potential outside the limits of these areas, we remain focused on our main therapeutic categories.

The third key component of our business strategy is our ability to optimize the market potential of established brands through clinically meaningful product enhancements. This brand enhancement, or product line extension strategy, is currently being successfully adopted by many of the world's largest pharmaceutical companies as they look for ways to protect and further exploit the significant clinical and marketing investments they have made in establishing high value brands. The strategy is based on leveraging the marketability of an existing, well-established in-market brand through the development of a new and improved or enhanced formulation.

We have already implemented this strategy through our acquisition of the market-leading Cardizem® family of products and the launch of Cardizem® LA, as well as through gaining access to the Wellbutrin franchise through a strategic agreement with GSK. We are pursuing the same strategy with the purchase of the Vasotec® and Ativan® brands, and the development of new and improved versions. We intend to continue to exploit our drug delivery technology assets and rich pipeline by entering into multi-faceted agreements with leading global pharmaceutical companies. Under these agreements we will employ our drug delivery expertise to the development of enhanced formulations or product line extensions of established branded products that provide competitive advantages in the marketplace. We may manufacture and supply these new products to third parties for a significant percentage of the product's net sales. These enhanced products could also be marketed by our own sales force, by our partners, or co-promoted as specific circumstances and market conditions warrant.

We will also investigate and take advantage of promising opportunities to acquire in-market products from strategic partners. Our agreements with GSK are an example of this type of transaction. Under the term of these agreements, we licensed our once-daily formulation of the antidepressant Wellbutrin XL to GSK in return for a manufacturing and supply contract for this product. We also acquired the rights to distribute GSK's topical antiviral Zovirax® product line in U.S. and we acquired the rights to co-promote GSK's existing Wellbutrin SR product in the U.S. from January 1, 2002 until March 31, 2003. In addition, we acquired the Canadian rights to Wellbutrin SR and Zyban and thereby plan to launch Wellbutrin XL in the Canadian market.

Our Business Process

Implementation of our business strategy is achieved through a three-step process designed specifically to leverage our research, development and drug delivery technology asset base. The three steps essentially involve *identification*, *development* and *commercialization* of promising controlled-release pharmaceutical products.

The process begins with the *identification* of unmet patient needs and drug compounds that effectively treat (or have the potential to treat) chronic medical conditions, that compete in large and growing markets (such as our target therapeutic categories cardiovascular (including Type II diabetes) CNS and pain management and, most importantly, that can be enhanced through the application of our proprietary drug delivery technologies to provide distinct clinical and competitive advantages. This includes the acquisition of established brand name medications that have significant brand equity in terms of proven efficacy, excellent safety profiles, physician acceptance, current usage by large patient populations, name recognition and proven marketability. Examples of this approach include our acquisitions of the Cardizem®, Vasotec® and Ativan® product lines in the U.S. and Cardizem® in Canada. In each case, we acquired existing products with strong brand equity to which we believe significant clinical, compliance or convenience enhancements can be achieved through the application of our drug delivery technologies and the development of line extension products.

The next step in the process is product *development*. This involves the efficient and timely advancement of promising products through clinical testing, late stage development and regulatory approval into the manufacturing stage. This is facilitated through our internal research and development, clinical testing, regulatory approval and manufacturing capabilities.

The third step in the process is product *commercialization*. Our structure provides us with a number of commercialization options. Each option is carefully evaluated based on the product and the existing competitive and marketing environments. For instance, in cases where an out-licensing agreement may result in shortened time to market, eliminate potential litigation, increased profitability and/or provide us with immediate access to already established brand name medications, this option will be selected. Examples of this type of transaction include our agreement in 1995 with Forest, for the commercialization of Tiazac® in the U.S., and in 2001 with GSK for the commercialization of Wellbutrin XL. (See Chronology of Strategic Events.)

Alternatively, we have the option to commercialize these products through our own North American sales operations, as we have done successfully with Tiazac® in Canada. We also have the option of acquiring well-established existing brands and exploiting a line extension or improved formulation through our internal sales force. The development and launch of Cardizem® LA in the U.S. is representative of this strategy. Pipeline products incorporating this strategy include Vasotec® and Ativan®.

The realignment and optimization of our U.S. primary care sales force has provided Biovail with a sales and marketing infrastructure from which to commercialize its portfolio of development-stage products. In addition, our two specialty sales forces (cardiovascular/nephrology and dermatology/Ob-Gyn) are expected to allow us to access the key opinion leaders (the specialist physicians) that greatly influence the prescribing patterns of primary care physicians. We believe this makes Biovail an attractive licensing partner for pharmaceutical or biotechnology companies seeking to commercialize their innovative products. We will remain focused on our core therapeutic categories cardiovascular disease, CNS disorders and pain management, while maintaining the flexibility to exploit other select niche markets. This focused approach will allow our sales force to develop expertise in therapeutic areas, maximize resource allocations and improve sales call targeting and frequency.

Industry Overview

The pharmaceutical industry has experienced significant growth over the past several years. This growth has been affected by factors such as: increasing enrollment in HMOs and growth in managed care, an aging and more health-aware population, several major new drugs bringing significant therapeutic benefits, and increasing use of novel marketing approaches such as direct-to-consumer advertising.

IMS reports that the total U.S. prescription drug market was approximately \$216 billion in 2003, an increase of 11.5% over the \$191 billion for 2002. The industry is undergoing a period of consolidation. It is estimated by IMS that during the years 2004-2008, branded products with estimated 2003 sales in excess of \$52 billion will lose patent protection. In 2003 alone, the figure was \$13 billion. To replace these revenues and lessen their

dependence on internal development programs, the large pharmaceutical companies are increasingly entering into strategic licensing arrangements with specialty pharmaceutical companies and augmenting their product pipelines by the acquisition of smaller specialty companies with valuable research and development programs and technologies. They are also developing strategies to defend themselves against generic competition through innovative approaches to extension of brand life-cycles, exclusivity periods and product differentiation.

The larger companies are increasingly focusing their marketing resources on large revenue drugs (generally in excess of \$500 million annual revenue) and accordingly are therefore sometimes willing to divest themselves of smaller, non-strategic products in niche therapeutic areas. According to IMS, in 2003 approximately 19% of U.S. market sales revenues were derived from branded drugs with revenues less than \$100 million. This affords a significant opportunity for smaller companies to acquire or in-license valuable brand name drugs and to revitalize these franchises through the application of novel delivery forms and technologies.

According to IMS, prescription growth for 2003 in the U.S. pharmaceutical market for all forms of controlled-release drugs was in excess of 6.6%. The oral dosage controlled-release segment of the market generated approximately \$19.6 billion of revenues in 2003, an increase of 20% over the prior year. The impetus for growth in this segment comes from the proliferation of branded drugs at or near patent expiration and new product launches.

Controlled-release products are formulated to release the drug's active ingredient gradually and predictably over a 12 to 24 hour period. These formulations provide for: (1) greater effectiveness in the treatment of chronic conditions through more consistent delivery of the medication; (2) reduced side effects; (3) greater convenience and (4) higher levels of patient compliance due to a simplified dosage schedule as compared to that of immediate-release drugs.

There are significant technical barriers to entry into the development of controlled-release drugs, with only a limited number of companies possessing the required expertise and technologies. Despite the therapeutic advantages of controlled-release drugs versus their immediate-release counterparts, many pharmaceutical companies have not made the additional investment to develop a controlled-release version of a product while their immediate-release version is under patent protection.

The pharmaceutical industry is subject to ongoing political pressure to contain the growth in spending on drugs and to expedite and facilitate bioequivalent competition to branded products. In the U.S., Medicare prescription drug coverage changes may be implemented in the next two to three years. Companies oriented towards improved drug delivery and bioequivalents could benefit from the market focus on cost-containment and therapeutic value.

For most of the 1990s, the FDA evidenced an accommodative stance to NDAs and ANDAs. Relatively fast drug approvals reflected corporate funding of NDA reviews and the political imperative of bringing bioequivalent competition to the market place. As a result of several high profile drug withdrawals over the past several years, there is now evidence of a more cautious stance from the FDA, as approval times appear to be slowing. This stance may operate to the benefit of drug delivery and bioequivalent drug companies whose products are viewed as rapid and lower cost methods of bringing safe new products to the market.

Our Products

Originally, due to limited resources, our products were licensed early in the development cycle to third party pharmaceutical companies who controlled the clinical trials, regulatory process, manufacturing and sale of our products in return for payment of licensing fees and revenue sharing. However, since the beginning of our evolution into a fully-integrated pharmaceutical company in the mid-1990s, we have been involved in all aspects of the drug development process, from formulation and development to clinical testing, regulatory filing, manufacturing, marketing, promotion and distribution. This integrated approach results in operational synergies, increased flexibility and cost efficiencies, as well as greater revenues. To date we have developed and filed with appropriate regulatory agencies more than 25 products utilizing advanced drug delivery technologies, which have been commercialized in over 50 countries.

Product Revenue Reporting Format

Beginning in the third quarter of 2003, we began reporting our product revenue in a structure that differs from reporting prior to this period. We believe this new reporting format provides greater transparency and clarity, and allows for improved tracking of our financial performance. The new financial reporting has been structured into the following five categories:

1. Promoted products
2. Biovail Pharmaceuticals Canada (BPC)
3. Wellbutrin XL
4. Legacy products
5. Generics

We also provide a subtotal of core products which includes: Promoted products, BPC and Wellbutrin XL, as this represents the part of our business that we either actively promote and/or have organically developed and licensed to third parties who promote them.

Promoted Products

This category refers to the group of products that Biovail actively promotes in the U.S. In 2003, these products were Cardizem® LA (launched in April 2003), Teveten®, Teveten® HCT (launched in March 2003), Zovirax® Ointment and Zovirax® Cream (launched in July 2003). We expect these products to remain the focus of our U.S. sales team in 2004. Cardizem® LA, the first Biovail-developed product to be launched in the U.S. through our own sales and marketing infrastructure, will remain the primary focus of our care sales force and our cardiovascular/nephrology specialty sales representatives. We believe recent efforts to promote managed care pull-through should result in prescription volume growth for this innovative product. With respect to the Teveten® line, promotional efforts and ongoing managed care initiatives are expected to drive growth in 2004. The Zovirax® line, which continues to dominate the topical herpes market should benefit from the detailing efforts of our new dermatology / Ob-Gyn specialty sales force.

Biovail Pharmaceuticals Canada

This revenue category includes all products sold and marketed in Canada. In 2003, BPC's 78-member sales force marketed Tiazac®, Monacor®, Retavase and Celexa® via a co-promotion agreement with Lundbeck Canada Inc., which helped the product become one of the fastest growing serotonin reuptake inhibitor ("SSRI") in the country, to physicians across Canada. In addition, during 2003 GSK marketed Wellbutrin® SR and Zyban in Canada on our behalf, pursuant to our December 2002 acquisition of the products. With the termination of the co-promotion agreement for Celexa® at the end of 2003, BPC assumed the marketing and sales promotion of Wellbutrin® SR and Zyban effective January 1, 2004.

Wellbutrin XL

This revenue item was established to provide greater visibility on the performance of this key product manufactured by Biovail for GSK. Launched in September 2003 by GSK, Wellbutrin XL captured 30% of all bupropion prescriptions by the end of the year. Having surpassed initial penetration expectations, Wellbutrin XL continues to make inroads in the U.S. antidepressant market, capturing in excess of 40% of bupropion prescriptions in less than seven months on the market. Pursuant to our manufacturing and supply agreement with GSK, we receive a three-tiered supply price that is based on GSK's net sales of Wellbutrin XL in any given year. The thresholds are reset at the beginning of the year. In the lowest tier, we receive a supply price of less than 25% of GSK's net sales. In the second tier, the supply price escalates to a value between 25% and 30% of GSK's net sales. In the highest tier, the supply price is greater than 30%. As our manufacturing costs remain relatively fixed throughout the year, our gross margins will be positively impacted as the thresholds are passed.

Legacy Products

This category includes the U.S. products that we do not actively promote. For the most part, these are products that have been genericized and generate revenue streams that are declining modestly, as expected. However, within this category are several products with large prescription bases such as Ativan® and Vasotec®, where clinical enhancements, once developed and approved should enable us to grow these franchises and capitalize on their long-established brand names. The development of Cardizem® LA is an example of the successful execution of this strategy, where we leveraged the strong brand equity associated with the Cardizem® name in launching an innovative new drug into an established and attractive market (the U.S. hypertension treatment market). Other products in this reporting category include Cardizem® CD, Tiazac®, Isordil®, Vaseretic®, Cedax® and Rondec®.

Generics

This category is comprised of those products that are distributed in the U.S. for Biovail by Teva. In 2003, these included bioequivalent formulations of Cardizem® CD, Adalat CC, Procardia XL, Voltaren XR and Trental. Despite a modest (less than 10%) decrease in prescription volume for these products in 2003, revenues were down considerably more (44%), as a result of Teva lowering inventory levels. Looking forward, although generic products are no longer a key area of focus for us, we currently have four ANDA submissions before the FDA for Dilacor XR, Verelan, Tegretol and Procardia XL 90 mg. Certain of these ANDA products are candidates for out-licensing should they receive regulatory approval.

Product Revenues (in 000's)

Category	2002	2003				
		Q1	Q2	Q3	Q4	Full-Year
Promoted Products						
Cardizem® LA	\$	\$	\$ 21,553	\$ 6,165	\$ 20,025	\$ 47,743
Teveten®	11,744	11,270	2,074	6,764	2,133	22,241
Zovirax®	96,517	25,601	17,998	47,146	11,689	102,434
	108,261	36,871	41,625	60,075	33,847	172,418
BPC	32,565	19,003	19,689	23,078	23,427	85,197
Wellbutrin XL			8,073	8,223	48,636	64,932
	140,826	55,874	69,387	91,376	105,910	322,547
Core Products	323,626	40,585	63,612	68,249	36,414	208,860
Legacy	181,534	30,455	24,731	20,359	25,946	101,491
Generics						
Total	\$ 645,986	\$ 126,914	\$ 157,730	\$ 179,984	\$ 168,270	\$ 632,898

BIOVAIL PRODUCTS

The following table summarizes our products that have been commercialized.

Product	Therapeutic Area	Indications	Therapeutic Market Size
Promoted Products U.S.			
Cardizem® LA	Cardiovascular	Hypertension / angina	\$14.9 billion
Teveten®	Cardiovascular	Hypertension	\$14.9 billion
Teveten® HCT	Cardiovascular	Hypertension	\$14.9 billion
Zovirax® Cream	Antiviral	Herpes labialis (cold sores)	\$1.1 billion
Zovirax® Ointment	Antiviral	Genital herpes	\$1.1 billion
Promoted Products Canada			
Monacor	Cardiovascular	Hypertension	\$1.8 billion
Tiazac®	Cardiovascular	Hypertension / angina	\$1.8 billion
Retavase	Cardiovascular	Acute myocardial infarction	\$43 million
Wellbutrin SR	CNS	Depression	\$0.9 billion
Zyban®	CNS	Smoking cessation	\$13 million
Marketed by Licensed Partners			
Tiazac® ⁽¹⁾	Cardiovascular	Hypertension / angina	\$14.9 billion
Wellbutrin XL ⁽²⁾	CNS	Depression	\$13.6 billion
Legacy Products			
Ativan®	CNS	Anxiety	\$0.9 billion
Cardizem® CD	Cardiovascular	Hypertension / angina	\$14.9 billion
Cedax®	Antimicrobial	Respiratory infections	\$2.2 billion
Isordil®	Cardiovascular	Angina	\$0.3 billion
Rondec®	Allergy	Cough, cold, allergy	\$1.1 billion
Vasotec®	Cardiovascular	Hypertension / congestive heart failure	\$14.9 billion
Vaseretic®	Cardiovascular	Hypertension / congestive heart failure	\$14.9 billion
Bioequivalent (generic) Products			
Adalat CC (nifedipine extended release) ⁽³⁾	Cardiovascular	Hypertension / angina	\$14.9 billion
Cardizem CD (diltiazem controlled release) ⁽³⁾	Cardiovascular	Hypertension / angina	\$14.9 billion
Procardia XL (nifedipine extended release) ⁽³⁾	Cardiovascular	Hypertension / angina	\$14.9 billion
Tiazac (diltiazem) ⁽⁴⁾	Cardiovascular	Hypertension / angina	\$14.9 billion
Trental (pentoxifylline) ⁽³⁾	Cardiovascular	Peripheral vascular disease	\$0.2 billion
Voltaren XR (diclofenac controlled release) ⁽³⁾	Inflammation	Arthritis	\$8.5 billion

(1) Tiazac® is distributed by Forest Laboratories, Inc. in the United States.

(2) Wellbutrin XL is marketed by GSK in the U.S.

(3) Distributed by Teva.

(4) Distributed by Forest.

Core Products

We have developed numerous controlled-release and FlashDose® drugs which, when commercialized are marketed directly through our BPC marketing division in Canada, as in the case of Tiazac®, or through BPI's U.S. sales and marketing infrastructure, as in the case of

Cardizem® LA, or that are commercialized through licensees.

Promoted Products

BPI, our U.S. marketing and sales division, performs sales and marketing activities for our products as well as for products licensed from third parties. During 2003, as part of our ongoing strategy to build a stronger presence in the U.S. market, the decision was made to relocate BPI's corporate headquarters from Raleigh, North Carolina to Bridgewater, New Jersey. This relocation places BPI in the heart of the pharmaceutical corridor between New York and Philadelphia. In addition, a new U.S. leadership team was established with the

hiring of a number of experienced pharmaceutical executives. We believe this action was necessary to further advance our evolution into a significant North American pharmaceutical company. Initiatives undertaken by the new management team include the realignment and optimization (including improving coverage of geography and targeting of physicians) of BPI's primary care sales force and the creation of two new specialty sales forces (of 63 representatives each) — one focusing on cardiovascular and nephrology specialists, the other on dermatologists and Ob-Gyns.

BPI's realigned 475-member primary care sales force will promote Cardizem® LA, Teveten®, Teveten® HCT, Zovirax® Ointment and Zovirax® Cream to general practitioners across the U.S. The cardiovascular/nephrology specialty sales representatives will promote Cardizem® LA and the Teveten® line of products to the key specialists in cardiovascular / nephrological medicine; while the dermatology / Ob-Gyn representatives will promote the Zovirax® line to specialists in those fields. In both cases, these specialist physician populations represent a new target audience for BPI, and should lead to an increase in prescriptions for BPI's promoted products. An early indication of this success is Cardizem® LA's continued penetration of the U.S. Calcium Channel Blocker ("CCB") market despite the loss of detailing efforts of 250 Reliant sales representatives in December 2003.

BPI is developing a significant marketing presence in the world's largest pharmaceutical market. With an optimized overall sales force numbering approximately 600 representatives, BPI is well positioned as sales and marketing partner for smaller pharmaceutical / biotechnology companies seeking to out-license their products. In addition, our maturing development pipeline should deliver an ongoing supply of new products for our sales force.

Cardizem® LA (diltiazem)

Cardizem® branded products have been leading medications in the CCB category of cardiovascular drugs for more than 20 years. In 2003, the CCB market was valued at \$4.4 billion, of which once-daily diltiazem products represented \$818 million. These once-daily products generated 19.1 million prescriptions in the U.S. in 2003, of which 11.9 million were written for Cardizem®, representing a market of \$476 million.

In April 2003, BPI launched Cardizem® LA. Cardizem® LA is a novel, graded extended-release formulation of diltiazem HCl that provides 24-hour blood pressure control with a single daily dose and offers physicians a flexible dosing range from 120mg to 540mg. Cardizem® LA is the only diltiazem product labeled to allow administration in either the morning or evening. With evening administration, clinical trials have shown Cardizem® LA improved reduction in blood pressure in the early morning hours, which is when patients may be at the greatest risk of significant cardiovascular events, such as heart attack, stroke, and death due to cardiovascular events.

Teveten® (eprosartan) and Teveten® HCT (eprosartan-hydrochlorothiazide)

Teveten® is indicated for the treatment of hypertension (high blood pressure). Teveten® belongs to a class of antihypertensive drugs known as angiotensin receptor blockers ("ARBs"). Total U.S. sales of all ARB products in 2003 were \$3.5 billion. Teveten® blocks the vasoconstrictor and aldosterone-secreting effects of angiotensin II by selectively blocking the binding of angiotensin II to the AT₁ receptor found in many tissues (e.g., vascular smooth muscle, adrenal gland). Solvay Pharmaceuticals Marketing and Licensing AG ("Solvay") first launched Teveten® in November 1999. We acquired the U.S. marketing rights to Teveten® and Teveten® HCT in March 2002. BPI relaunched Teveten® in the U.S. market in June 2002.

In March 2003, BPI launched Teveten®/HCT, a combination of Teveten® and the diuretic hydrochlorothiazide.

Zovirax® Ointment / Zovirax® Cream (acyclovir)

Zovirax® Ointment 5% is a topical formulation of a synthetic nucleoside analogue active against herpes viruses. Each gram of Zovirax® Ointment contains 50mg of acyclovir in a polyethylene glycol (PEG) base. This product is indicated in the management of initial genital herpes and in limited non-life threatening mucocutaneous herpes simplex infections in immunocompromised patients. Zovirax® Ointment was originally

launched in 1982 by Burroughs Wellcome, although it has not been promoted by GlaxoWellcome since 1997, Zovirax® Ointment remains the market leader with a 56% share of total prescriptions for topical anti-herpes products in 2003.

Zovirax® Cream was approved by the FDA in December 2002 and launched by BPI in July 2003. Zovirax® Cream is a topical antiviral medication used for the treatment of herpes labialis (cold sores). The Zovirax® franchise had 59% share of the total prescriptions for topical anti-herpes products in 2003, generating revenues of \$102 million.

Legacy Products

In addition to the products promoted by the BPI sales force, BPI also sells our legacy products Cardizem® CD, Ativan®, Isordil®, Vasotec®, Vaseretic®, Rondec®, and Cedax® to wholesalers and retailers. These products were either genericized prior to our acquisition of them or represent small, non-core market opportunities (as in the case of Cedax® and Rondec®). Accordingly, there is no sales force promotion supporting these products. In the case of Vasotec® and Ativan®, our strategy is to leverage the strong brand equity associated with these products in the development and commercialization of novel / enhanced formulations.

Vasotec® (enalapril maleate)/Vaseretic® (enalapril maleate hydrochlorothiazide)

Vasotec® and Vaseretic® have been highly recognized in the treatment of hypertension, symptomatic congestive heart failure, and asymptomatic left ventricular dysfunction for nearly 20 years. Vasotec® is the maleate salt of enalapril, the ethyl ester of a long-acting angiotensin converting enzyme ("ACE") inhibitor, enalaprilat. Enalapril is a pro-drug; following oral administration, it is bioactivated by hydrolysis of the ethyl ester to enalaprilat, which is the active ACE inhibitor.

Vaseretic® combines Vasotec® and a diuretic, hydrochlorothiazide. The product is indicated for the treatment of hypertension.

For the 12-month period ending December 2003, the ACE inhibitor market achieved total sales of approximately \$4.1 billion with 137 million total prescriptions dispensed, a 3% increase over the previous year. Vasotec® (branded and generic) is one of the most widely prescribed ACE inhibitors and is one of the top five most recognized cardiovascular brands. Vasotec® lost its market exclusivity in August 2000 and its revenues have since been eroded by generic competition. Nevertheless, in 2003, there were 16.8 million prescriptions written for enalapril.

We are currently developing an enhanced formulation of Vasotec® with an improved 24-hour kinetic profile and have begun development of several fixed dose combinations of enalapril and other active ingredients.

Ativan® (lorazepam)

Ativan® is a benzodiazepine lorazepam, indicated for the management of anxiety disorders or for the short-term relief of anxiety or anxiety associated with symptoms of depression. Biovail acquired U.S. marketing rights to Ativan® from Wyeth in June 2003. The market for anxiety treatments was in excess of \$923 million for the 12 months ended December 31, 2003, with Ativan® (lorazepam) generating 22.3 million prescriptions. Sales of benzodiazepine products were in excess of \$668 million for the 12 months ended December 31, 2003.

We are currently developing enhanced formulations of Ativan®, in addition to novel dosage forms potentially targeting new indications.

Isordil® (isosorbide dinitrate)

Isordil® (isosorbide dinitrate) (ISDN), a coronary vasodilator, is indicated for the prophylaxis of ischemic heart pain associated with coronary insufficiency (angina pectoris). Biovail acquired U.S. marketing rights to Isordil® from Wyeth in June 2003. Isordil® dilates the blood vessels by relaxing the muscles in their walls. Oxygen flow improves as the vessels relax, and chest pain subsides. Isordil® helps to increase the amount of exercise prior to the onset of chest pain and can help relieve chest pain that has already started or prevent pain expected from a strenuous activity such as walking up a hill or climbing stairs.

Sales of nitrate products were in excess of \$305 million for the 12 months ended December 31, 2003. Total prescriptions for orally administered nitrates were in excess of \$20 million in 2003. ISDN (brand and bioequivalent) represented nearly 2.4 million of these prescriptions (representing 12% market share) for the 12 months ended December 31, 2003.

Tiazac® (diltiazem)

Tiazac® belongs to a class of drugs called CCBs used in the treatment of hypertension and angina, which generated U.S. sales of \$4.4 billion for the 12 months ended December 31, 2003. Within the CCB market, once-daily diltiazem products accounted for approximately \$818 million of this total. After being introduced in the U.S. in February 1996, Tiazac® reached a peak market share of 21.1% (measured as a percentage of total prescriptions for once-daily diltiazem products) in 2002. At December 31, 2003, this figure was 13.3% as the product faced its first generic competitors in April 2003.

We licensed the right to market Tiazac® in the U.S. to Forest in September 1995 and the formal product launch took place in February 1996. We act as the exclusive manufacturer of the product and receive contractually determined manufacturing fees. Forest provides us with a royalty payment on net sales of Tiazac®. Upon the onset of generic competition for Tiazac®, we launched a competing generic version through Forest under a profit sharing arrangement.

Cedax® (cefibuten) & Rondec® (carbinoxamine/pseudoephedrine)

Cedax® is a patented, third generation, broad-spectrum oral cephalosporin antibiotic indicated for the treatment of chronic bronchitis, otitis media and pharyngitis/tonsillitis. Cedax® was launched by Schering-Plough in 1996 and achieved peak sales in 1997 of \$52 million. Schering-Plough manufactures the product for us. Rondec® is a prescription decongestant indicated for relief of nasal congestion associated with allergy or the common cold. Rondec® was developed by Abbott Laboratories and acquired from Dura Pharmaceuticals.

In December 2003, as part of the restructuring of our U.S. commercial operations, we evaluated our future interest in our Cedax® and Rondec® product lines. BPI intends to focus its therapeutically aligned sales efforts on cardiovascular products, such as Cardizem® LA and Teveten®, as well as Zovirax®. Without continued promotion, the economic viability of Cedax® and Rondec® is substantially lower, as these products require significant marketing and sales efforts in order to maintain market share. We evaluated the current and forecasted market share for Cedax® and Rondec® and determined that the products were no longer strategic.

BPC Products

BPC's head office is located at our corporate headquarters in Mississauga, Ontario, Canada. BPC is dedicated to providing high quality, cost effective branded pharmaceuticals to Canadian health care professionals and their patients. BPC's sales force consists of 8 Regional Sales Managers, 48 Primary Care Representatives and 22 Specialty Care Representatives, who currently detail select products to approximately 10,000 physicians across Canada. In addition to marketing products we have developed, BPC has adopted a business strategy of selling branded drug products through in-licensed products. We believe that this strategy, combined with our portfolio of existing and new branded products utilizing our advanced drug delivery technologies, positions BPC to become a significant marketing presence in the Canadian market.

BPC's product portfolio strategy is to focus on drugs and therapies for the primary care market including drugs for the treatment of cardiovascular and CNS diseases. Both therapeutic areas represent rapidly growing market segments, offering a multitude of opportunities for acquiring third party licenses. Product revenues in 2003 were derived from the sale of the following key products: Tiazac®, Cardizem® CD, Retavase and Monocor®, in addition to Wellbutrin SR and Zyban, which were marketed by GSK. In 2003, BPC also earned revenues for co-promoting Celexa® (an antidepressant) pursuant to an agreement with Lundbeck Canada Inc., ("Lundbeck") which was terminated on December 31, 2003.

In 2004, BPC has assumed full promotional responsibility for Wellbutrin SR and will market the product directly to physicians in Canada. We anticipate leveraging this repositioning strategy and the associated increase in awareness of the Wellbutrin brand with the future launch of Wellbutrin XL in Canada. Other products

currently marketed by BPC include Tiazac® and Retavase. Zyban, a prescription product indicated for use in smoking cessation, is marketed through non-sales force direct marketing activities.

Tiazac® (diltiazem)

As described above, Tiazac® is a CCB used in the treatment of hypertension and angina. Tiazac® is a once-daily formulation of diltiazem that delivers smooth blood pressure control over a 24 hour period. As a non-dihydropyridine CCB, Tiazac® provides specific renal-protective benefits as well as blood-pressure reduction, which is particularly important for diabetic hypertensive patients. The Canadian market for CCBs for the year ending December 31, 2003, was valued at approximately \$428 million, an increase of 9.6% versus the previous year. At the end of 2003, Tiazac® held a 43.0% share of the once-daily diltiazem market. We have developed a novel formulation of Tiazac®, known as Tiazac® XC (marketed as Cardizem® LA in the U.S.), that is currently awaiting regulatory approval in Canada.

Wellbutrin SR (bupropion) / Zyban (bupropion)

Biovail acquired the Canadian rights to Wellbutrin SR and Zyban from GSK in December 2002. Wellbutrin SR (sustained-release bupropion) is indicated as first-line therapy for the treatment of depression. Wellbutrin's antidepressant activity appears to be mediated by noradrenergic and dopaminergic mechanisms making it different than selective serotonin reuptake inhibitors and other known antidepressant agents. In addition to antidepressant efficacy, Wellbutrin provides patients with the additional benefits of increased cognition and motivation and a low propensity to cause sexual dysfunction, a common side effect of some other antidepressant therapies. Zyban, the same molecule as Wellbutrin SR, is indicated as an aid to smoking cessation treatment.

In 2003, GSK marketed Wellbutrin SR and Zyban in Canada on our behalf, as our detailing efforts were focused on Celexa® pursuant to a co-promotion agreement with Lundbeck. With the termination of the Celexa® agreement at the end of 2003, BPC assumed full responsibility for Wellbutrin® SR, and has been detailing the product since January 1, 2004. The Canadian market for antidepressants was valued at \$630 million in 2003, an increase of 14.6% over the previous year. Zyban is marketed through non-sales force mediated direct marketing activities. The 2003 Canadian prescription drug market for smoking cessation aids is estimated at \$9 million.

Retavase® (reteplase recombinant)

Retavase®, licensed from Centocor Inc., is a tissue plasminogen activator used in thrombolytic therapy. The medication is administered to patients immediately after the incidence of acute myocardial infarction (AMI or heart attack) and acts to clear arterial blockage. The thrombolytic market in Canada for the year ended December 31, 2003 was estimated to be approximately \$29 million, a decrease of 23.5% over the previous year, as a result of a market shift away from fibrinolytics. Accordingly, BPC has decided to shift its strategy towards other high potential opportunities. Retavase remains a strategic product within the BPC portfolio.

Monacor® (bisoprolol fumarate)

Monacor® is a cardio-selective beta-blocker indicated for the treatment of mild to moderate hypertension and congestive heart failure. Monacor® first faced generic competition in July 2003. The beta-blocker market in Canada was valued at approximately \$125 million in 2003.

Celexa® (citalopram)

Celexa® is a member of the selective SSRI class of antidepressants. BPC co-promoted Celexa® to Canadian primary care physicians until December 31, 2003 and helped the product become one of the fastest growing SSRIs in Canada. With the termination of the co-promotion agreement for Celexa® at the end of 2003, BPC assumed marketing and sales responsibility for Wellbutrin SR effective January 1, 2004.

Generic Products

We have an agreement with Teva for the development and marketing of a number of our generic controlled-release products. Products currently marketed by Teva include generic versions of Cardizem® CD (diltiazem),

Adalat CC (nifedipine), Procardia XL (nifedipine), Trental (pentoxifylline) and Voltaren XR (diclofenac). Biovail manufactures these products and receives a share of profits after deducting manufacturing, sales and distribution costs.

The primary products in our controlled-release generics portfolio; Cardizem® CD, Adalat CC and Procardia XL, represent technically challenging molecules to work with. These technological barriers may inhibit others from developing generic version of the products. This competitive landscape allows for pricing flexibility, mitigating the price discounting that can often reach 90% in the generic pharmaceuticals industry.

In March 2004, Biovail invoked a dispute resolution mechanism contained in the distribution agreement with Teva and commenced legal proceedings through arbitration against Teva. These proceedings stem from perceived improprieties by Teva in calculating the net sales from the basket of generic products exclusively licensed to them, from which Biovail and Teva are to calculate their respective financial entitlements. These perceived improprieties were detected through a formal audit conducted by an independent accounting firm. The Company expects these proceedings to be completed within a year from their commencement.

Pipeline Products

We are working to develop clinically enhanced branded versions of a number of therapeutic compounds. Our development efforts have resulted in the recent submission of New Drug Applications for Ralivia ER (once-daily tramadol), Ralivia FlashDose® (orally disintegrating tramadol) and Glumetza, our once-daily Metformin. We anticipate filing one NDA, as well as initiating four late-stage clinical trials by year-end 2004. In addition, our FlashDose® zolpidem, and fluoxetine products have received FDA approvable letters. Beyond these, our pipeline products are in various stages of development. These pipeline products marketed by others had aggregate U.S. sales in excess of \$13.8 billion for the twelve months ended December 31, 2003. The current versions of these pipeline programs do carry some residual development risk, and as such, we do not anticipate the commercialization of all of these products. In addition, we routinely review and prioritize our pipeline as new products are added, which can result in the discontinuation or delay of lower-priority development programs. This is a normal course of business in the pharmaceutical industry. In 2003, our pipeline review/reprioritization resulted in the postponement or discontinuation of several programs, including our 5-FU and simvastatin EA products. Our current pipeline of disclosed development programs is shown below, followed by a brief discussion of our late-stage programs.

Development Pipeline Products*

Product	Indication	Current Status
Cardiovascular		
Tiazac® XC (diltiazem)	Hypertension	Regulatory Review (Canada)
Glumetza (metformin)	Type II Diabetes	Regulatory Review (U.S. and Canada)
Vasotec® XL (enalapril)	Hypertension	Under Development
Teveten® SB (eprosartan)	Hypertension	Under Development
Central Nervous System		
Zolpidem ODT	Sleep Disorders	FDA Approvable Letter
Fluoxetine ODT	Depression	FDA Approvable Letter
Venlafaxine SB	Depression	Under Development
Wellbutrin® XL 450 mg (bupropion)	Depression	Under Development
Wellbutrin® XL Line Extension (bupropion)	Depression	Under Development
Ativan® ODT (lorazepam)	Anxiety	Under Development
Pain Management		
Ralivia ER (tramadol)	Pain	Regulatory Review (U.S.)
Ralivia FlashDose® (tramadol)	Pain	Regulatory Review (U.S.)
Tramadol / Acetaminophen ODT	Pain	Under Development
Sumatriptan ODT	Migraine	Under Development
Other		
Acyclovir CR	Herpes	Under Development

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 20-F

Product	Indication	Current Status
Procardia XL 90 mg (nifedipine)	Hypertension/Angina	Regulatory Review (U.S.)

* *Biovail is currently developing a number of undisclosed and other pipeline products*

Late-Stage Pipeline Programs

Pain Management

Ralivia ER / Ralivia FlashDose® (Tramadol)

A four to six-times daily immediate-release formulation of Tramadol, introduced in March 1995 by Johnson & Johnson ("J&J"), is sold in the U.S. under the brand name Ultram. In June 2002, generic competitors were introduced in the U.S. and now dominate the molecule's prescription volume. In 2003, the U.S. Tramadol market (including Ultram, its generics and Ultracet – a combination product) was valued at approximately \$413 million, representing a total of 16.8 million prescriptions.

Indication: Tramadol is indicated for the treatment of a moderate to moderately severe pain – a common symptom of many diseases, and generally seen in everyday clinical practice.

Clinical Efficacy: Tramadol is one of a number of analgesics, which are among the most effective and valuable medications for the treatment of chronic pain. Tramadol's minimal propensity to induce adverse effects is an advantage over other morphine-like agents. For example, relative to morphine, Tramadol causes less dependence and less respiratory depression. Tramadol also appears to be a promising drug for post-operative pain relief.

Two long-term safety studies conducted on patients with chronic, nonmalignant pain demonstrated the efficacy of the Tramadol compound in a variety of pain conditions.

Potential Enhancement: Beyond the therapeutic and compliance benefits of one-daily dosing (relative to the current formulations that are dosed up to six times daily), Ralivia ER – product could potentially feature a faster titration regimen. With respect to our Ralivia FlashDose® product, the orally disintegrating tablets offer compliance, convenience and potentially other benefits, particularly for those patients who have difficulty swallowing, including the elderly, who are more likely to suffer from chronic pain.

Status of Development: Biovail recently filed New Drug Applications for both Ralivia ER and Ralivia FlashDose® with the FDA. We have indicated our desire to out-license these products and are in active discussions with potential partners.

Market Size: The combined market for narcotic and non-narcotic analgesics generated U.S. sales of \$13.9 billion for the twelve months ended December 31, 2003. This broader market includes the Cox-2 inhibitors such as Celebrex and Vioxx, in addition to narcotic products such as Oxycontin, Duragesic and Percocet.

Sumatriptan FD

Sumatriptan is a 5-HT₁-receptor agonist (commonly referred to as triptans) marketed in the U.S. by GSK under the brand name Imitrex. In 2003, the product generated U.S. revenues of \$1.1 billion, with over 6 million prescriptions dispensed.

Indication: Sumatriptan is indicated for the acute treatment of migraine attacks with or without aura in adults.

Clinical Efficacy: The efficacy of Imitrex tablets in the acute treatment of migraine headaches was demonstrated in 3 randomized, double-blind, placebo-controlled studies. In all 3 trials, the percentage of patients achieving headache response 2 and 4 hours after treatment was significantly greater among patients taking Imitrex at all doses compared to those who received a placebo.

Potential enhancement: The FlashDose® technology may provide the convenience of enabling administration of sumatriptan with or without water. In addition, unlike other Triptans in ODT form, our formulation does not show a significant prolongation of T_{max} (time to maximum concentration) compared to the immediate-release tablet.

Status of Development: We have successfully completed pilot bioavailability studies and are currently in the process of conducting pivotal bioavailability trials.

Market size: In 2003, the U.S. anti-migraine market was valued at \$1.9 billion, representing a 7% increase over the prior year. Over 13 million prescriptions for these therapeutics were dispensed in 2003. Other products in this class include Amerge, Axert, Frova, Maxalt and Zomig.

Central Nervous System (CNS) Disorders

Zolpidem FD

Zolpidem was launched in 1993 and is now marketed in the U.S. by Sanofi-Synthelabo under the brand name Ambien. In 2003, the product generated U.S. revenues of \$1.1 billion, representing growth of 21% relative to the prior year period.

Indication: Zolpidem is indicated for the short-term treatment of insomnia.

Clinical Efficacy: Until the early 1990s pharmacological intervention for insomnia usually resorted to short-term treatment with benzodiazepines. These drugs were less than ideal due to their propensity to induce tolerance and subsequent rebound insomnia at higher dosages, coupled with a long half-life leading to lingering effects on next-day motor functioning. Zolpidem can substantially reduce these adverse effects.

Potential enhancement: The FlashDose® technology may provide the convenience of enabling administration of zolpidem with or without water.

Status of Development: We filed an NDA with the FDA in December 2001 and received an approvable letter for this product in November 2002. There are patents in place inhibiting our independent commercialization of this product until October 2006.

Market Size: The sleep disorder market in the U.S was valued at \$1.8 billion for the twelve-month period ended December 31, 2003. Ambien was the market leader with sales of \$1.3 billion during the same period. Other competitors include Sonata, Restoril (brand and generics) and Halcion (brand and generics).

Wellbutrin XL 450 mg / Bupropion Line Extension

A four-times daily immediate-release formulation of bupropion was introduced in July 1989 by GSK under the brand name Wellbutrin. In 1996, GSK launched a twice-daily controlled-release formulation of bupropion, Wellbutrin SR . In September 2003, GSK launched Wellbutrin XL , a once-daily formulation of bupropion developed by us. The Wellbutrin franchise generated U.S. sales of \$1.9 billion for the twelve months ended December 31, 2003.

Indication: Bupropion is indicated for the symptomatic relief of depressive illness. Incidences of major depression are frequently encountered by primary care physicians. Depression may occur in neurosis as well as in mood disorders and is a manifestation of major psychiatric illness.

Clinical Efficacy: Bupropion has proven to be effective in the treatment of depression. An open, uncontrolled study of 3,167 patients at 105 sites showed that functional status improved in patients treated with Wellbutrin SR for up to 56 days. This improvement was highly correlated with improvement in clinical symptoms.

Potential enhancement: Our 450 mg formulation would complement the existing in-market doses of 150 mg and 300 mg, providing physicians with greater flexibility in their treatment regimens. We are not disclosing the enhancement opportunities we are pursuing with our bupropion line extension product.

Status of Development: Development efforts for a 450 mg formulation of bupropion are currently in the process development / scale-up stage. We are not disclosing the development status of our undisclosed bupropion line extension / enhancement program.

Market Size: Sales of anti-depressant products totaled \$13.6 billion for the twelve months ended December 31, 2003. Bupropion is classified as a new generation anti-depressant. The anti-depressant market consists of four major drug categories: new generation antidepressants, SSRIs/SNRIs (Selective Serotonin Reuptake Inhibitors/Selective Norepinephrine Reuptake Inhibitors), tricyclic antidepressants, and monoamine

oxidase inhibitors. Major marketed brands include Lexapro (escitalopram), Paxil (paroxetine), Zoloft (sertaline) and Effexor XR (venlafaxine).

Venlafaxine SB

A two times daily immediate-release formulation of venlafaxine, introduced by Wyeth in March of 1994, is marketed in the U.S. under the brand name Effexor. In 1997, Wyeth introduced a controlled-release formulation marketed as Effexor XR. U.S. sales of Effexor and Effexor XR were approximately \$2.3 billion for the twelve months ended December 31, 2003.

Indication: Venlafaxine is indicated for the treatment of depression and general anxiety disorder.

Clinical Efficacy: The efficacy of Effexor XR in the treatment of depression was established in 8 and 12-week controlled trials of outpatients whose diagnoses corresponded most closely to the DSM-III-R or DSM-IV category of major depressive disorder.

The efficacy of Effexor XR as a treatment for general anxiety disorder (GAD) was established in two 8-week, placebo-controlled, fixed-dose studies, one 6-month, placebo-controlled, fixed dose study, and one 6-month, placebo-controlled, flexible-dose study in outpatients meeting DSM-IV criteria for GAD.

In two head-to-head comparison studies, people with major depression treated with Effexor (venlafaxine) were more likely to recover completely than those treated with either Prozac (fluoxetine) or Zoloft (sertraline).

Potential Enhancement: We believe a superbioavailable version of venlafaxine could allow us to reduce the administered dose, while achieving comparable blood levels and efficacy; or allow the attainment of higher blood levels without a substantial change in capsule size.

Status of Development: Formulation development and pilot bioavailability studies were successfully completed. We are currently in the formulation optimization and process development stage.

Market Size: Sales of anti-depressant products totaled \$13.6 billion for the twelve months ended December 31, 2003. The anti-depressant market consists of four major drug categories: new generation antidepressants, SSRIs/SNRIs (Selective Serotonin Reuptake Inhibitors/Selective Norepinephrine Reuptake Inhibitors), tricyclic antidepressants, and monoamine oxidase inhibitors. Major marketed brands include Prozac (fluoxetine), Paxil (paroxetine), Zoloft (sertaline), Effexor XR (venlafaxine) and Wellbutrin (bupropion).

Cardiovascular (including Type II Diabetes)

Glumetza

A two to three times daily immediate-release formulation of metformin, introduced in April 1995 by Bristol-Myers Squibb ("BMS"), is sold in the U.S. under the brand name Glucophage. In October 2000, BMS introduced a controlled-release metformin formulation marketed as Glucophage XR. U.S. sales of Glucophage and Glucophage XR were approximately \$1.8 billion for the twelve months ended December 31, 2003.

Indication: Metformin is indicated for the treatment of diabetes mellitus which cannot be controlled by proper dietary management, exercise and weight reduction or when insulin therapy is not appropriate. Diabetes is a common disorder in which there are inappropriately elevated blood glucose levels and a variety of end organ complications leading to impaired kidney function and accelerated atherosclerosis.

Clinical Efficacy: Clinical advantages of metformin include achieving control of elevated blood sugar levels without exacerbating weight gain, which is a common side effect of other anti-diabetic treatments. Metformin differs from the sulfonylureas in that it does not elevate insulin secretion and does not produce abnormally low blood sugar levels.

In controlled trials, metformin has shown efficacy in lowering elevated blood sugar levels in the treatment of diabetes mellitus. In one such study of 289 obese patients with non-insulin dependent diabetes, poorly controlled with diet, the patients were given metformin or a placebo. Blood sugar levels were on average 29% lower in patients receiving metformin than in patients receiving a placebo. Furthermore, total cholesterol, LDL

and triglyceride concentrations decreased in patients receiving metformin, but did not change in patients receiving a placebo.

Potential Enhancement: Our clinical program was conducted with a faster titration regimen, allowing patients to get to their optimal dose more quickly.

Status of Development: In collaboration with our partner, Depomed who have developed a 500 mg strength we have developed a once-daily metformin product 1000 mg strength using our technology. We have successfully completed two large Phase III trials, and in April 2004 submitted an NDA under section 505(b)(1) to the FDA, and an NDS to the TPD for both of these dosage forms.

Market Size: The Type II diabetes market represented approximately \$5.7 billion in U.S. sales for the twelve months ended December 31, 2003, a 9% increase relative to the prior year. Beyond Glucophage and its generics, other Type II diabetes therapeutics include Glucotrol XL, Avandia and Actos.

Teveten® SB (eprosartan)

Teveten®, an ARB, was approved by the FDA in December 1997 and launched by Solvay in 1999. In March 2002, Biovail acquired U.S. marketing rights to Teveten® and Teveten® HCT (a combination product of eprosartan and the diuretic hydrochlorothiazide). Having not been promoted by Solvay at the time of acquisition, Biovail relaunched Teveten® through its own U.S. sales force in May 2002. Following FDA approval in February 2003, Teveten® HCT was launched in March 2003.

Indication: Teveten® is indicated for the treatment of hypertension.

Clinical Efficacy: The safety and efficacy of Teveten® have been evaluated in controlled clinical trials worldwide. The antihypertensive effects of Teveten® were demonstrated in five randomized studies involving 1,111 patients. At study endpoint, patients treated with Teveten® at doses of 600 mg to 1200 mg given once daily experienced significant decreases in sitting systolic and diastolic blood pressure, with differences from placebo of approximately 5-10/3-6 mmHg. In addition, a number of large studies are ongoing, with data expected in 2004 that could further differentiate the product.

Potential enhancement: An enhanced bioavailability formulation of Teveten® would allow for a lower administered dose of the product, potentially reducing the size of the dosage form and improving our cost of goods for this product. This would also facilitate the development of additional combination products involving Teveten®.

Status of Development: Our development program for Teveten® SB is currently in the pilot bioavailability stage.

Market Size: The broader U.S. hypertension treatment market was valued at \$14.9 billion in 2003, a 5% increase relative to 2002. Within that market, ARBs represented the fastest growing segment with revenues increasing 30% to \$3.5 billion. Other products competing in the ARB market include Diovan, Cozaar, Avapro and Benicar.

Vasotec® XL

A once to twice daily formulation of enalapril maleate, launched in 1986 by Merck under the name Vasotec®, is now sold by BPI. Vasotec® belongs to a class of antihypertensive medications known as ACE inhibitors. U.S. sales of Vasotec® and its generic equivalents were \$124 million for the 12 months ended December 31, 2003.

Indication: Vasotec® is indicated for the treatment of hypertension, congestive heart failure and asymptomatic left ventricular dysfunction.

Clinical Efficacy: Vasotec® is effective alone or in combination with other antihypertensive agents, especially thiazide-type diuretics. ACE activates a hormone called angiotensin. Once activated, angiotensin causes blood vessels to constrict resulting in high blood pressure and a strain on the heart.

ACE inhibitors act on the renin-angiotensin-aldosterone pathway, inhibiting the conversion of Angiotensin I to Angiotensin II. This results in dilated blood vessels and lower blood pressure. Even in people with normal blood pressure, blocking the activation of angiotensin and dilating blood vessels is effective for treatment of the other conditions listed above.

In clinical studies, administration of Vasotec® to patients with hypertension of severity ranging from mild to severe, resulted in a reduction of both supine and standing blood pressure.

Potential Enhancement: We are in the process of developing a formulation of Vasotec® with an improved 24-hour kinetic profile. Currently, Vasotec® is being dosed more than once-per-day more than 30% of the time it is prescribed. We believe that an enhanced formulation of Vasotec® will offer an improved clinical benefit as compared to the current formulation. We intend to commercialize this product under the well-recognized Vasotec® brand name (Vasotec® XL). We are also pursuing the development of combination products featuring Vasotec® (enalapril).

Status of Development: We are currently in the process of formulation development with our Vasotec® XL program. Pilot biostudies are is ongoing.

Market Size: For the 12-month period ending December 2003, the ACE inhibitor market achieved total sales of \$3.1 billion, a decrease of 18% relative to 2002 as generic competition increased within the class. Other products in this class include Altace, Accupril, Lotensin and Zestril. The broader hypertension treatment market was valued at \$14.9 billion in 2003, a 5% increase relative to 2002.

Anti-Viral Products

Acyclovir CR

A five-times daily formulation of acyclovir sodium, taken for 7 to 10 days, introduced in February 1985 by what is now GSK, is marketed in the U.S. under the brand name Zovirax®. In October 2001, Biovail acquired the U.S. rights to the topical formulations of Zovirax® (Ointment and Cream) from GSK. Zovirax®, including its generic oral formulations, generated 5.8 million prescriptions and revenues of \$160 million in 2003.

Indication: Acyclovir is indicated for the acute treatment of herpes zoster (shingles); initial episodes and the management of recurrent episodes of genital herpes; and chickenpox.

Clinical Efficacy: Double-blind, placebo controlled studies with patients with initial genital herpes have demonstrated that orally administered Zovirax® significantly reduced the duration of acute infection and duration of lesion healing. The duration of pain and new lesion formation was decreased in some patient groups.

Double-blind, placebo-controlled studies in patients with frequent recurrences (6 or more episodes per year) have shown that orally administered acyclovir given daily for 4 months to 10 years prevented or reduced the frequency and/or severity of recurrences in greater than 95% of patients.

In a double-blind, placebo-controlled study of immunocompetent patients with localized cutaneous zoster infection, acyclovir shortened the times to lesion scabbing, healing, and complete cessation of pain, and reduced the duration of viral shedding and the duration of new lesion formation.

Potential Enhancement: Our development efforts for oral acyclovir are targeting a shorter treatment regimen relative to the onerous schedule of the current in-market product. This could potentially enhance therapeutic outcomes, in addition to improving patient convenience/compliance.

Status of Development: The development efforts for acyclovir CR are ongoing and we expect to initiate Phase III clinical trials for this product in the second half of 2004.

Market Size: The U.S. herpes treatment market was valued at \$1.1 billion in 2003, representing 21% growth relative to 2002. Of this, \$898 million was derived from oral herpes therapeutics. Other products in this market include Valtrex and Famvir. Oral formulations of Zovirax® generated revenues of \$36.4 million in 2003.

Contract Research Division (CRD)

The CRD is a division of Biovail that provides us and other pharmaceutical companies with a broad range of Phase I and Phase II clinical research services. These involve principally conducting pharmacokinetic studies and bioanalytical laboratory testing to establish a drug's bioavailability or its bioequivalence to another drug moiety. The CRD has an independent Institutional Review Board that assures that all studies are conducted in an ethical and safe manner, without compromising the health of the human subjects participating in these studies.

Operating as an independent business unit in Toronto, Ontario, the CRD is located in a 41,000 square foot stand-alone facility owned by us and a 10,500 square foot leased facility. These facilities include a fully equipped bioanalytical laboratory, a department of biopharmaceutics and a newly constructed 12-bed Phase I First-in-Man Unit part of a 230-bed bio-clinic to house live-in human subjects.

To date, the CRD has designed and conducted in excess of 2,500 bioavailability, bioequivalence and/or drug interaction studies. The therapeutic areas in which studies have been completed include cardiovascular disease, cardiopulmonary, bone and joint disease, pain management, infectious diseases, central nervous system, gastroenterology and endocrinology. In addition, the CRD has performed Phase I First-in-Man studies to establish the safety on new molecular entities.

The CRD has a database in excess of 30,000 healthy male and female volunteers for potential study enrollment as well as a large inventory of disease related patient groups, including post-menopausal women, renal-impaired and diabetic patients. The bioanalytical laboratory continues to add to its inventory of over 100 developed and validated assays. The operations of the CRD are subject to full compliance with the rules and regulations of the FDA, TPD and other comparable foreign regulatory bodies.

Other Biovail Divisions

We develop and manufacture nutraceutical and food ingredient products incorporating our proprietary technologies in our Nutravail division. Large-scale manufacture of nutraceutical products is currently handled through third party contractors but a variety of higher value flavour encapsulations, gums and gum bases are developed and manufactured at our Sterling, Virginia facility.

Research and Development

As part of the recent relocation of BPI from Raleigh to Bridgewater, we accommodated certain of our senior personnel from our commercial and development operations in this new facility. This initiative should ensure that our pipeline development efforts are targeted at the most attractive market opportunities. Accordingly, under this new structure, pipeline expansion / development decisions will be based on the identification of markets with unmet patient needs.

Our staff of scientists has expertise in all aspects of the drug development process, from pre-formulation studies and formulation development to scale-up and manufacturing. We have successfully developed appropriate delivery systems for pharmaceutical compounds exhibiting a wide range of solubility and hydrophobicity characteristics.

Subsequent to the acquisition in November 1999 of BTL, formerly Fuisz, we concluded that it was appropriate to integrate much of the research and development being conducted in Mississauga, Ontario, Canada facility with that being conducted at the BTL Chantilly, Virginia facility. This consolidation was carried out during 2000 such that only formulation development work is now carried out in Mississauga. The Chantilly facility comprises 91,000 square feet of administrative, laboratory and manufacturing space. In addition we own a 27,000 square foot research and development facility in Dublin, Ireland.

As part of our business strategy we enter into research and development contracts with third party formulators and developers to expand our development pipeline opportunities. These third party developers are typically paid with a combination of development milestone payments and royalty payments. In some cases, we have an ownership interest or an option to acquire an ownership position in the developer. In no case are we responsible for any of the developers' third party liabilities, nor have we guaranteed any obligations of the developers, nor are we required under any circumstances to exercise any of our options.

Technology

We have numerous proprietary drug delivery technologies that we use to develop controlled-release, enhanced/modified absorption and rapid dissolve products and also have access to technologies of our development partners through licensing agreements. These technologies enable us to develop both branded and generic pharmaceutical products. Our formulations for these products are either patented or proprietary. Accordingly, other generic manufacturers may be inhibited from duplicating our products without infringing our patented or proprietary rights or because of the difficulty of duplicating our formulations.

Oral controlled-release technology permits the development of specialized oral drug delivery systems that improve the absorption and utilization by the human body of a variety of pharmaceutical compounds. Release patterns are characterized as zero order, which indicates constant drug release over time, or first order, which indicates decreasing release over time. These systems offer a number of advantages, in particular, allowing the patient to take only one or two doses a day. This, combined with enhanced therapeutic effectiveness, reduced side effects, improved compliance and potential cost effectiveness, makes controlled-release drugs ideally suited for the treatment of chronic conditions.

Our controlled-release technologies can provide a broad range of release profiles, taking into account the physical and chemical characteristics of a drug product, the therapeutic use of the particular drug and the optimal site for release of the basic drug in the gastrointestinal tract (the "GI tract"). The objective is to provide a delivery system allowing for a single dose per 12 to 24 hour period, while assuring gradual and controlled-release of the subject drug at a suitable location(s) in the GI tract.

Our rapid dissolve (FlashDose®) formulations contain the same basic chemical compound found in the original branded products. The dry chemical compounds are encapsulated in microspheres utilizing our CEFORM technology. Our Shearform technology is used to produce matrices that are subsequently processed into amorphous fibers which, when blended with the CEFORM microspheres, can be compressed into rapid dissolve formulations including FlashDose® tablets. We can also make FlashDose® tablets without using our Shearform technology. The benefits of rapid dissolve formulations include the ease of administration for the elderly, young children or people with disease states who may have difficulty swallowing tablets or capsules.

Our enhanced technology platform is unique in a sense that we use various formulation, physico-chemical tools and apply a combination of these tools to a drug in order to increase the solubility, increase the amount absorbed, control the pre-systemic metabolism and/or increase the rate of absorption with or without modification of the total amount of drug into the bloodstream.

We use proprietary drug delivery platforms, as described below, involving matrix tablets or multiparticulate beads in capsules. These platforms are capable of delivering a wide variety of drug compounds in controlled-release and rapid dissolve oral dosage formulations.

Dimatrix

Dimatrix is a diffusion controlled matrix technology for water-soluble drugs in the form of tablets. The drug compound is uniformly dispersed in a polymer matrix. The mechanism of release involves the swelling of polymers within the matrix, thus enabling the drug to be dissolved and released by diffusion through an unstirred boundary layer. The release pattern is characterized as first order as the rate of drug diffusion out of the swollen matrix is dependent upon the concentration gradient.

Macrocap

Macrocap consists of immediate-release beads made by extrusion/spheronization/pelletization techniques or by layering powders or solutions on nonpareil seeds. Release modulating polymers are sprayed on the beads using various coating techniques. The coated beads are filled in hard gelatin capsules. Drug release occurs by diffusion associated with bioerosion or by osmosis via the surface membrane. The release mechanism can be pH activated or pH independent. The beads can be formulated to produce first order or zero order release.

Consurf

Consurf is a zero order drug delivery system for hydrophilic and hydrophobic drugs in the form of matrix tablets. The drug compound is uniformly dispersed in a matrix consisting of a unique blend of polymers. The mechanism of release involves the concurrent swelling and erosion of the matrix such that a constant surface matrix area is maintained during transit through the GI tract, resulting in zero order release.

Multipart

Multipart consists of a tablet carrier for the delivery of controlled-release beads that preserves the integrity and release properties of the beads. The distribution of the beads is triggered by disintegration of the tablet carrier in the stomach. Drug release from the beads can be pH activated or pH independent and can occur by disintegration or osmosis. The beads can be formulated to produce first or zero order release.

CEFORM

CEFORM is a microsphere technology used to produce uniformly sized and shaped microspheres of a wide range of pharmaceutical compounds. The microspheres are nearly perfectly spherical in shape, typically have a diameter of 50-600 microns or more precisely 150-180 microns for FlashDose®, and allow for high drug content. CEFORM microspheres are produced using a continuous, single-step and solvent-free manufacturing process that can be used to formulate drugs that are generally thermally unstable because of the very brief application of heat and the wide range of temperatures which can be used in the manufacturing process. Depending on the desired release characteristics and oral dosage format, CEFORM microspheres can be formulated for controlled-release, enhanced absorption, delayed release, rapid absorption or taste masking.

Shearform

Shearform is used to produce matrices of saccharides, polysaccharides or other carrier materials that are subsequently processed into amorphous fibers or flakes and recrystallized to a predetermined level. This process is used to produce rapid dissolve formulations, including FlashDose®. Shearform can also be applied to food product ingredients to provide enhanced flavoring.

Smartcoat

Smartcoat is a technology Biovail acquired from and developed with Pharma Pass (see Chronology of Strategic Events). This technology allows the manufacturing of very high potency controlled-release tablets, allowing small size tablets while controlling the release over a 24-hour period. A thin, very strong molecular diffusion membrane controls the release and the rate can be adapted to a Zero order or Weibull function.

Chronotabs

Chronotabs are made of Multipart or Smartcoat tablets particularly adapted to chronotherapy (the science of treating diseases that follow the body's circadian rhythms), using a second layer of smart polymers made of dry- or film-coating in order to optimize the active drug absorption profile for a bed time administration.

Zero Order Release System ("ZORS")

ZORS is a technology that allows us to develop Zero Order kinetic systems, based on a proprietary controlled release matrix coating. ZORS allows Biovail to develop controlled release tablets that alleviate food

effect in drugs known to have their pharmacokinetic profile influenced by meals. This technology was developed and patented by Pharma Pass.

Oral Colonic delivery system

The Oral Colonic delivery system is a novel technology acquired from Pharma pass. The technology uses a dosage form characterized by a dual triggering of drug release (known as DUALex). A review of the literature shows that products designed for oral delivery but that release their active ingredient in the intestine are based on either (1) a pH sensitive polymer coating, (2) enzymatic degradation or (3) osmotic pressure. However, the variability of the intestinal medium creates a challenge with respect to predictability and reproducibility of the drug's release characteristics. Our oral colonic delivery system combines two of the three mechanisms, thereby increasing the precision of the drug release triggering.

Chronology of Strategic Events

In September 1995, we licensed the right to market Tiazac® in the U.S. to Forest and the formal product launch took place in February 1996. Under a 16-year supply agreement which also commenced December 1995, we act as the exclusive manufacturer of Tiazac® for Forest and receive contractually determined manufacturing fees. The license agreement with Forest provides for a royalty payment of 8% of its net sales of Tiazac® for a period of 16 years, commencing December 1995. In April 2003, a generic version of Tiazac® was launched in the U.S. market. As a result, we launched our own generic formulation through a profit sharing agreement with Forest.

In July 1997, Intelligent Polymers Limited ("IPL") was formed primarily to develop once-daily controlled-release branded versions of selected drugs whose chemical patents and/or exclusivity periods had or were about to expire and which were marketed only in immediate-release form, or in controlled-release form requiring multiple daily dosing. IPL's products included once-daily versions of Bupropion, Tramadol and Metformin. We expect that such products will be marketed under distinct brand names. We had the right to acquire directly or indirectly all of the equity of IPL. On December 29, 2000, we exercised our option to purchase all of the equity of IPL.

In December 1997, we entered into an agreement with Teva for the development and marketing in the U.S. of specific generic oral controlled-release products. These include products that have already been approved by the FDA as well as products under development. The terms of the agreement call for us to manufacture the products and share the profits after deduction of manufacturing costs and an allowance for selling and distribution expenses incurred by Teva. Products currently commercialized and marketed under this agreement include bioequivalent controlled-release versions of Trental (pentoxifylline), Cardizem® CD (diltiazem), Voltaren XR (diclofenac), Adalat CC (nifedipine), Procardia XL (nifedipine) and Verelan. In addition, ANDAs have been filed for bioequivalent versions of Dilacor XR, and Procardia XL 90mg.

Our November 1999, acquisition of Fuisz Technologies Ltd. ("Fuisz"), renamed Biovail Technologies Limited ("BTL") has given us several proprietary drug delivery technologies, including taste masking, rapid dissolve and enhanced absorption, which we are applying in the development of FlashDose® versions of several oral dosage, controlled-release branded products. In 2000, we consolidated our research and development activities at BTL's Chantilly, Virginia location.

In October 2000, we acquired DJ Pharma, renamed BPI, a U.S. pharmaceutical sales and marketing company with approximately 300 sales representatives and several drug brands marketed and sold to physicians for the treatment of respiratory and allergy conditions and skin and soft tissue infections. During 2002, we expanded our U.S. sales force from approximately 300 to approximately 550 in preparation for the launch of new products, such as Cardizem® LA and Teveten HCT in 2003.

In December 2000, we acquired the rights to and benefits from, the Cardizem® family of products for the Canadian, U.S. and Puerto Rican markets from Aventis. Cardizem® branded products, used in the treatment of hypertension and angina, have been a leading line in the CCB category of cardiovascular drugs for over twenty years. Cardizem CD is being manufactured on our behalf by Aventis subject to a three-year supply arrangement, which is currently the subject of extension negotiations.

In October 2001, we licensed to GSK a novel controlled-release, once-daily formulation of bupropion HCl (Wellbutrin XL) for sales and distribution on a worldwide basis excluding Canada. Bupropion HCl, which is marketed by GSK for the treatment of depression as Wellbutrin and for smoking cessation as Zyban, was previously sold in sustained-release ("SR") or twice-daily, and immediate-release or four-times daily, dosage formats. Under the terms of the Wellbutrin XL agreement, we manufacture and supply Wellbutrin XL to GSK for a share of the revenue generated by net sales of the product. Together with GSK, we co-promoted Wellbutrin SR in the U.S. until March 31, 2003.

Effective January 1, 2002, Biovail acquired from GSK the exclusive distribution rights for Zovirax® (acyclovir) Ointment and, upon approval by the FDA, Zovirax® Cream in the U.S. Zovirax® is an anti-viral topical product. Zovirax® Ointment is indicated for the treatment of herpes, and Zovirax® Cream is indicated for the treatment of cold sores. In January 2003, we received FDA approval for Zovirax® Cream. GSK will continue to manufacture and supply Zovirax® Ointment and Zovirax® Cream to us. In December 2002, we and GSK agreed to extend the Zovirax® distribution agreement from 10 to 20 years.

In March 2002, we acquired from Solvay the rights to Teveten® and Teveten® HCT in the U.S. Teveten® is an ARB for the treatment of hypertension and is indicated for use either alone or in conjunction with other antihypertensive medications. Solvay will continue to manufacture and supply Teveten® and Teveten® HCT to us, and will assist in qualifying a Biovail facility to achieve the transition of the manufacturing process. Solvay will continue to manufacture and market Teveten® and Teveten® HCT in areas outside of the U.S. We formed a joint business development committee with Solvay to discuss future clinical and product development options that could enhance the performance or expand the utilization of Teveten®. We are currently in development for an enhanced bioavailability formulation of Teveten. Solvay has the option to acquire, for worldwide markets excluding the U.S., all potential future modifications and innovations developed by Biovail for Teveten®.

In April 2002, Biovail acquired a 15% equity interest in Ethypharm S.A. ("Ethypharm") and it obtained the rights to market six products under development by Ethypharm. The products under development included Ethypharm's Flashtab versions of tramadol ("Tramadol FT") and combination of tramadol and acetaminophen ("Tramadol/Acetaminophen FT").

In May 2002, we acquired from Merck the rights to Vasotec® (enalapril) and Vaseretic® (enalapril with hydrochlorothiazide) in the U.S. We also acquired the fixed-dose combination New Drug Application ("NDA") of enalapril in combination with diltiazem malate. Merck will continue to manufacture and supply Vasotec® and Vaseretic® to us. We will make semi-annual payments to Merck over a five-year term for minimum product quantities and a minimum fixed royalty (regardless of the actual product supplied). We will also pay Merck royalties on any future sales of any life cycle products developed and marketed in the U.S. We also entered into a separate development agreement with Merck to develop a new dosage format of a Merck product.

In May 2002, we acquired from Depomed the rights to manufacture and market a once daily metformin HCl product. This product, Glumetza used in the treatment of diabetes, has successfully completed Phase III clinical trials. An NDA submission was made in April 2004.

In the third quarter of 2002, we entered into an agreement with Reliant to co-promote a number of existing Biovail products in the U.S. Approximately 650 of Reliant's sales representatives joined our sales representatives to promote Teveten® and other cardiovascular products through to the end of 2002. This agreement was expanded in the fourth quarter of 2002 whereby Reliant agreed to provide 250 sales representatives for three years to co-promote a range of our cardiovascular products including Cardizem® LA. In December 2003, we mutually agreed with Reliant to terminate Reliant's co-promotion of certain of our products effective December 31, 2003.

In December 2002, we acquired 100% of the outstanding interests of Pharma Pass LLC and 100% of the outstanding shares of Pharma Pass S.A. Through the acquisition of Pharma Pass, we extinguished any future milestone or royalty obligations that we may have had to Pharma Pass resulting from the approval and successful commercialization of any products under development, pursuant to the research and development agreements previously entered into between us and Pharma Pass. We obtained interests in certain licensed products including Tricor (fenofibrate) and generic omeprazole. We are entitled to royalties on sales of Tricor and a participating interest in the gross profit on sales of generic omeprazole. This agreement also added two new

drug delivery technologies to our portfolio, ZORS for increased drug delivery control and absorption, and an oral colonic delivery technology, which increases drug absorption in the upper colon and lower intestine.

In December 2002, we acquired the Canadian rights to Wellbutrin® SR and Zyban® from GSK. Through this agreement and upon marketing approval from Canadian authorities, we have the right to market our once-daily formulation of bupropion HCl as Wellbutrin XL in Canada. In support of the commercialization of Wellbutrin XL and under the terms of our agreement, we gain access to information and data from past and future clinical studies conducted by GSK.

During 2003, we launched 3 products, Teveten HCT in March, Cardizem LA in April and Zovirax Cream in July through our BPI sales and marketing organization and in September GSK launched our Wellbutrin XL product.

In April 2003, we launched Cardizem® LA, a once daily controlled and graded-release formulation of diltiazem for the treatment of hypertension, through our U.S. sales force. The approval of Cardizem® LA marked a major milestone for us as the first internally developed product launched by our own U.S. sales organization. Cardizem® LA is specifically formulated to provide increased protection in the early morning hours, when patients may be at the greatest risk of significant cardiac events, and smooth release over a full 24 hours. Cardizem® LA is manufactured in our facilities in Puerto Rico and Manitoba.

In April 2003, we acquired from Flamel exclusive North American rights to Flamel's oral controlled-release formulation of acyclovir (Genvir) used in the treatment of genital herpes. We intend to manufacture this product, upon FDA approval, using Flamel's proprietary controlled-release "Micropump" technology. We anticipate the start of Phase III clinical trials in the second half of 2004.

In April 2003, we entered into an agreement with Athpharma to acquire four cardiovascular products under development. The four products under development are Bisochron (bisoprolol), a beta-1 selective beta-blocker formulation for the treatment of hypertension, Isochron (isosorbide-5-mononitrate), a long-acting nitrate formulation for the treatment of angina, and Hepacol I (pravastatin) and Hepacol II (simvastatin), two liver-selective statin formulations for the treatment of high cholesterol. Athpharma will complete the development of these products. We will pay a portion of the development costs, and may make aggregate payments of approximately \$24,000,000 to Athpharma subject to the attainment of certain milestones.

In May 2003, we acquired from Wyeth the rights to Ativan®, indicated for the management of anxiety disorders, and Isordil® (isosorbide dinitrate), indicated for the prevention of angina pectoris due to coronary artery disease, in the U.S. We also acquired a license to use certain technologies relating to Wyeth's Canadian sublingual version of Ativan® to develop new Ativan® sublingual products to be sold in the U.S. Wyeth will manufacture and supply Ativan® and Isordil® to us for three years.

In July 2003, we formed a limited liability company with Pharma Pass II, LLC ("PPII") ("BNC-PHARMAPASS") to develop enhanced formulations of three products. These products were Coreg (carvedilol), a beta-blocker indicated for the treatment of congestive heart failure, a super bioavailable version of Teveten® and Flomax (tamsulosin), indicated for the treatment of benign prostatic hyperplasia.

Regulatory Affairs and Quality Assurance

Our Corporate Regulatory Affairs Department is involved in the development and registration of each product and has prepared product submissions for regulatory agencies in the U.S., Canada, the United Kingdom and the European Union. This department also coordinates all data and document management, including amendments, supplements and adverse events reporting. Our Quality Assurance Department seeks to ensure that all stages of product development and production fully comply with good clinical, laboratory and manufacturing practices.

Patents and Proprietary Rights

We have not routinely sought patents on our controlled-release technologies because the filing of certain patents may provide potential competitors with information relating to proprietary technology, which may enable such competitors to exploit information related to such technology that is not within the confines of the

protection of the patent. However, we do file patents relating to the application of our technologies to specific drug compounds for specific uses. Accordingly, novel products arising from our development efforts are typically patented, thereby providing intellectual property rights and associated market protection.

Historically, we have relied on trade secrets, know-how and other proprietary information. While certain of our licensors have sought patents on controlled-release technology licensed to them, there can be no assurance that any patents will be issued or, if issued, that the manufacture, use, sale, importation or offer for sale of such patented matter will not infringe upon other patents or technology. Our ability to compete effectively with other companies will depend, in part, upon our ability to maintain the proprietary nature of our technology and to avoid infringing patents of others. To protect our rights in these areas, we require all licensors, licensees and significant employees to enter into confidentiality agreements. There can be no assurance, however, that these agreements will provide meaningful protection for our trade secrets, know-how or other proprietary information in the event of any unauthorized use or disclosure of such trade secrets, know-how or other proprietary information.

Manufacturing Facilities

We currently operate four modern, fully-integrated pharmaceutical manufacturing facilities located in Steinbach, Manitoba; Chantilly, Virginia; Dorado, Puerto Rico and Carolina, Puerto Rico. All of these facilities meet FDA-mandated good manufacturing practices. These facilities are inspected on a regular basis by regulatory authorities, and our own internal auditing team ensures compliance on an ongoing basis with such standards.

Our Steinbach, Manitoba facility totals 145,000 sq. ft. following the completion of a 47,000 square foot expansion during 2002 in preparation for manufacturing in 2003 of Wellbutrin XL. This new wing contains five main areas including a block of GMP rooms equipped with fluid bed granulation, bin blending, tableting, tablet coating and tablet printing equipment suitable for Wellbutrin XL (and other similar) products. This addition doubles the manufacturing capacity of the Steinbach facility, and was operational (GMP ready) in May 2003.

The Carolina, Puerto Rico facility totals 34,000 square feet, including 23,000 square feet of manufacturing capacity and 11,000 square feet of additional leased warehouse space. This plant is specially constructed for the high volume production of controlled-release beads.

The Dorado, Puerto Rico facility totaling 120,000 square feet, was acquired in 2001. During 2002, additional improvements were made to the facility including the completion of the laboratory expansion initiated in 2001. Additional equipment for the manufacturing of controlled-release and FlashDose® products was installed within the facility during 2002. This equipment expands manufacturing capacity to support production requirements. Packaging of Tiazac® commenced in the Dorado facility in 2002, after the "site transfer" was approved by FDA. A new warehouse and technology transfer expansion commenced in 2003 and will continue during 2004, adding 24,000 square feet to the facility.

The Dorado facility will be the primary manufacturing site for FlashDose® products. The focus of the FDA approved Chantilly, Virginia facility will be on R&D and technology transfer activities however this site remains an FDA approved facility and is available as an "alternate" or back-up site for the production of FlashDose® products.

For additional discussion regarding our manufacturing facilities see Item 4.D, "Property, Plant and Equipment".

Competition

The pharmaceutical industry is highly competitive and subject to rapid and significant technological change. Our products face competition from both conventional forms of drug delivery and controlled-release drug delivery systems developed, or under development, by other pharmaceutical companies. Many of these competitors have greater financial resources and marketing capabilities than we have. Our competitors in the U.S. and abroad are numerous and include, among others, major pharmaceutical and chemical companies, including, some of the licensees (or potential licensees) of our products, specialized contract research and research and development firms, universities and other research institutions. We believe that our controlled-

release technology combined with our strategy of funding and controlling all or most aspects of our controlled-release pharmaceutical business will provide the cost savings, efficiencies in product development and acceleration of regulatory filings necessary for us to compete effectively with such firms and institutions. Our competitors, however, may succeed in developing technologies and products that are as, or more, clinically or cost-effective than any that are being developed or licensed by us, or that would render our technologies and products obsolete or uncompetitive. In addition, certain of our competitors have greater experience than us in clinical testing and human clinical trials of pharmaceutical products and in obtaining FDA and other regulatory approvals.

Regulation

The research and development, manufacture and marketing of controlled-release pharmaceuticals are subject to regulation by U.S., Canadian and foreign governmental authorities and agencies. Such national agencies and other federal, state, provincial and local entities regulate the testing, manufacturing, safety and promotion of our products. The regulations applicable to our products may change as the currently limited number of approved controlled-release products increases and regulators acquire additional experience in this area.

U.S. Regulation

New Drug Application

We are required by the FDA to comply with NDA procedures for our branded products prior to commencement of marketing by us or our licensees. New drug compounds and new formulations for existing drug compounds which cannot be filed as ANDAs are subject to NDA procedures. These procedures include: (1) preclinical laboratory and animal toxicology tests; (2) scaling and testing of production batches; (3) an Investigational New Drug Application ("IND"), submission and acceptance of which is required before any human clinical trials can commence; (4) adequate and well controlled replicate human clinical trials to establish the safety and efficacy of a drug for its intended indication; (5) the submission of an NDA to the FDA; and (6) FDA approval of an NDA prior to any commercial sale or shipment of the product, including pre-approval and post-approval inspections of its manufacturing and testing facilities. If all of the data in the product application are owned by the applicant, the FDA will issue its approval without regard to patent rights that might be infringed or exclusivity periods that would affect the FDA's ability to grant an approval if the application relied upon data which the applicant did not own.

Preclinical laboratory and animal toxicology tests must be performed to assess the safety and potential efficacy of a product. The results of these preclinical tests, together with information regarding the methods of manufacture of the products and quality control testing, are then submitted to the FDA as part of an IND requesting authorization to initiate human clinical trials. Once the IND goes into effect, clinical trials may be initiated, unless a hold on clinical trials is subsequently issued by the FDA.

Clinical trials involve the administration of a pharmaceutical product to individuals under the supervision of qualified medical investigators that are experienced in conducting studies under "Good Clinical Practice" guidelines. Clinical studies are conducted in accordance with protocols that detail the objectives of a study, the parameters to be used to monitor safety and the efficacy criteria to be evaluated. Each protocol is submitted to the FDA and to an Institutional Review Board prior to the commencement of each clinical trial. Clinical studies are typically conducted in three sequential phases, which may overlap. In Phase 1, the initial introduction of the product into healthy human subjects, the compound is tested for absorption, safety, dosage, tolerance, metabolic interaction, distribution, and excretion. Phase 2 involves studies in a limited patient population with the disease to be treated to (1) determine the effectiveness of the product for specific targeted indications, (2) determine optimal dosage and (3) identify possible adverse effects and safety risks. In the event Phase 2 evaluations demonstrate that a pharmaceutical product is effective and has an acceptable safety profile, Phase 3 clinical trials are undertaken to further evaluate clinical efficacy of the product and to further test its safety within an expanded patient population at geographically dispersed clinical study sites. Periodic reports on the clinical investigations are required. We, or the FDA, may suspend clinical trials at any time if either party believes the clinical subjects are being exposed to unacceptable health risks. The results of the product development,

analytical laboratory studies and clinical studies are submitted to the FDA as part of an NDA for approval of the marketing and commercialization of a pharmaceutical product.

The above-described NDA procedures are premised on the applicant being the owner of, or having obtained a right of reference to, all of the data required to prove safety and efficacy. These NDAs are governed by 21 U.S.C. § 355(b)(1), also known as Section 505(b)(1) of the Food, Drug and Cosmetic ("FDC") Act.

Abbreviated New Drug Application

In certain cases, where the objective is to develop a generic version of an approved product already on the market in controlled-release dosages, an ANDA may be filed in lieu of filing an NDA. Under the ANDA procedure, the FDA waives the requirement to submit complete reports of preclinical and clinical studies of safety and efficacy and instead requires the submission of bioequivalency data, that is, demonstration that the generic drug produces the same effect in the body as its brand-name counterpart and has the same pharmacokinetic profile, or change in blood concentration over time. The ANDA procedure would be available to us for a generic version of a drug product approved by the FDA. In certain cases, an ANDA applicant may submit a suitability petition to the FDA requesting permission to submit an ANDA for a drug product that differs from a previously approved reference drug product (the "Listed Drug") when the change is one authorized by statute. Permitted variations from the Listed Drug include changes in: (1) route of administration, (2) dosage form, (3) strength and (4) one of the active ingredients of the Listed Drug when the Listed Drug is a combination product. The FDA must approve the petition before the ANDA may be submitted. An applicant is not permitted to petition for any other kinds of changes from listed drugs. The information in a suitability petition must demonstrate that the change from the Listed Drug requested for the proposed drug product may be adequately evaluated for approval without data from investigations to show the proposed drug product's safety or effectiveness. The advantages of an ANDA over an NDA include reduced research and development costs associated with bringing a product to market, and generally a shorter review and approval time at the FDA.

505(b)(2) Application Process

Pharmaceutical companies should submit a 505(b)(2) application for a change in a drug when approval of the application relies on the FDA's previous finding of safety and/or effectiveness for a drug. This mechanism essentially makes the FDA's conclusions that would support the approval of an ANDA available to an applicant who develops a modification of a drug that is not supported by a suitability petition. Regulation permits a 505(b)(2) applicant to rely on the FDA's finding of safety and effectiveness for an approved drug to the extent such reliance would be permitted under the generic drug approval provisions. This approach is intended to encourage innovation in drug development without requiring duplicative studies to demonstrate what is already known about a drug while protecting the patent and exclusivity rights for the approved drug.

Patent Certification and Exclusivity Issues

ANDAs are required to include certifications with respect to any patents that claim the Listed Drug or that claim a use for the Listed Drug for which the applicant is seeking approval. If applicable patents are in effect and this information has been submitted to the FDA, the FDA must delay approval of the ANDA until the patents expire. If the applicant believes it will not infringe the patents, it can make a patent certification to the holder of patents on the drug for which a generic drug approval is being sought, which may result in patent infringement litigation which could delay the FDA approval of the ANDA for up to 30 months. If the drug product covered by an ANDA were to be found by a court to infringe another company's patents, approval of the ANDA could be delayed until the patents expire. Under the Federal FDC Act, the first filer of an ANDA with a "non-infringement" certification is entitled to receive 180 days of market exclusivity. Subsequent filers of generic products would be entitled to market their approved product six months after the earlier of the first commercial marketing of the first filer's generic product or a successful defense of a patent infringement suit.

Patent expiration refers to expiry of U.S. patents (inclusive of any extensions) on drug compounds, formulations and uses. Patents outside the U.S. may differ from those in the U.S. Under U.S. law, the expiration of a patent on a drug compound does not create a right to make, use or sell that compound. There may be

additional patents relating to a person's proposed manufacture, use or sale of a product that could potentially prohibit such person's proposed commercialization of a drug compound.

The FDC Act contains non-patent market exclusivity provisions that offer additional protection to pioneer drug products and are independent of any patent coverage that might also apply. Exclusivity refers to the fact that the effective date of approval of a potential competitor's ANDA to copy the pioneer drug may be delayed or, in certain cases, an ANDA may not be submitted until the exclusivity period expires. Five years of exclusivity are granted to the first approval of a "new chemical entity." Three years of exclusivity may apply to products which are not new chemical entities, but for which new clinical investigations are essential to the approval. For example, a new indication for use, or a new dosage strength of a previously-approved product, may be entitled to exclusivity, but only with respect to that indication or dosage strength. Exclusivity only offers protection against a competitor entering the market via the ANDA and 505(b)(2) routes, and does not operate against a competitor that generates all of its own data and submits a full NDA under Section 505(b)(1) of the FDC Act.

If applicable regulatory criteria are not satisfied, the FDA may deny approval of an NDA or an ANDA or may require additional testing. Product approvals may be withdrawn if compliance with regulatory standards is not maintained or if problems occur after the product reaches the market. The FDA may require further testing and surveillance programs to monitor the pharmaceutical product that has been commercialized. Noncompliance with applicable requirements can result in additional penalties, including product seizures, injunction actions and criminal prosecutions.

Canadian Regulation

The requirements for selling pharmaceutical drugs in Canada are substantially similar to those of the U.S. described above, with the exception of the 505(b)(2) route.

Investigational New Drug Application

Before conducting clinical trials of a new drug in Canada, we must submit a Clinical Trial Application (CTA) to the TPD. This application includes information about the proposed trial, the methods of manufacture of the drug and controls, preclinical laboratory and animal toxicology tests on the safety and potential efficacy of the drug, and information on any previously executed clinical trials with the new drug. If, within 30 days of receiving the application, the TPD does not notify us that our application is unsatisfactory, we may proceed with clinical trials of the drug. The phases of clinical trials are the same as those described above under "U.S. Regulation New Drug Application."

New Drug Submission

Before selling a new drug in Canada, we must submit an NDS (New Drug Submission) or sNDS (Supplemental New Drug Submission) to the TPD and receive a Notice of Compliance (NOC) from the TPD to sell the drug. The submission includes information describing the new drug, including its proper name, the proposed name under which the new drug will be sold, a quantitative list of ingredients in the new drug, the methods of manufacturing, processing, and packaging the new drug, the controls applicable to these operations, the tests conducted to establish the safety of the new drug, the tests to be applied to control the potency, purity, stability and safety of the new drug, the results of biopharmaceutics and clinical trials as appropriate, the intended indications for which the new drug may be prescribed and the effectiveness of the new drug when used as intended. The TPD reviews the NDS or sNDS. If the submission meets the requirements of Canada's Food and Drugs Act and Regulations, the TPD will issue a NOC for the new drug.

Where the TPD has already approved a drug for sale in controlled-release dosages, we may seek approval from the TPD to sell an equivalent generic drug through an Abbreviated New Drug Submission (ANDS). In certain cases, the TPD does not require the manufacturer of a proposed drug that is claimed to be equivalent to a drug that has already been approved for sale and marketed, to conduct clinical trials; instead, the manufacturer must satisfy the TPD that the drug is bioequivalent to the drug that has already been approved and marketed.

The TPD may deny approval or may require additional testing of a proposed New Drug if applicable regulatory criteria are not met. Product approvals may be withdrawn if compliance with regulatory standards is not maintained or if problems occur after the product reaches the market. Contravention of Canada's Food and Drug Act and Regulations can result in fines and other sanctions, including product seizures and criminal prosecutions.

Proposals have recently been made that, if implemented, would significantly change Canada's drug approval system. In general, the recommendations emphasize the need for efficiency in Canadian drug review. Proposals include establishment of a separate agency for drug regulation and modeling the approval system on those found in European Union countries. There is no assurance, however, that such changes will be implemented or, if implemented, will expedite the approval of new drugs.

The Canadian government has regulations which can prohibit the issuance of an NOC for a patented medicine to a generic competitor, provided that the patentee or an exclusive licensee has filed a list of its Canadian patents covering that medicine with the Minister of Health and Welfare. After submitting the list, the patentee or an exclusive licensee can commence a proceeding to obtain an order of prohibition directed to the Minister prohibiting him or her from issuing an NOC. The minister may be prohibited from issuing an NOC permitting the importation or sale of a patented medicine to a generic competitor until patents on the medicine expire or the waiver of infringement and/or validity of the patent(s) in question is resolved by litigation in the manner set out in such regulations. There may be additional patents relating to a company's proposed manufacture, use or sale of a product that could potentially prohibit such company's proposed commercialization of a drug compound.

Certain provincial regulatory authorities in Canada have the ability to determine whether the consumers of a drug sold within such province will be reimbursed by a provincial government health plan for that drug by listing drugs on formularies. The listing or non-listing of a drug on provincial formularies may affect the prices of drugs sold within provinces and the volume of drugs sold within provinces.

Additional Regulatory Considerations

Sales of our products by our licensees outside the U.S. and Canada are subject to regulatory requirements governing the testing, registration and marketing of pharmaceuticals, which vary widely from country to country.

Our manufacturing facilities located at Steinbach, Manitoba; Chantilly, Virginia; and in Dorado and Carolina, Puerto Rico operate according to FDA and TPD mandated Good Manufacturing Practices. These manufacturing facilities are inspected on a regular basis by the FDA, the TPD, and other regulatory authorities. Our internal auditing team monitors compliance on an ongoing basis with FDA and TPD mandated good manufacturing practices. From time to time, the FDA, the TPD or other regulatory agencies may adopt regulations that may significantly affect the manufacture and marketing of our products.

In addition to the regulatory approval process, pharmaceutical companies are subject to regulations under provincial, state and federal law, including requirements regarding occupational safety, laboratory practices, environmental protection and hazardous substance control, and may be subject to other present and future local, provincial, state, federal and foreign regulations, including possible future regulations of the pharmaceutical industry. We believe that we are in compliance in all material respects with such regulations as are currently in effect.

C. Organizational Structure

The subsidiaries of the Company are detailed under "Subsidiary Information" in Item 10.I.

D. Property, Plant and Equipment

We own and lease space for manufacturing, warehousing, research, development, sales, marketing, and administrative purposes.

In 2003, we completed work on the 47,000 square foot expansion of our Steinbach, Manitoba manufacturing facility in order to increase production capacity in support of Wellbutrin XL production. In order to meet the

forecasted future production capacity we are planning to initiate an expansion in 2004 at the Steinbach facility to expand the facility by approximately 150,000 square feet to meet warehousing, laboratory, office and production requirements. Construction will be completed by the end of 2005. As part of the Dorado manufacturing facility upgrade we initiated construction of a new 23,000 square foot facility in support of laboratory, scale-up manufacturing and warehouse space with construction to be completed in early 2004. We have initiated activities at the Dorado plant for scale-up of production in support of products under development and have transitioned certain packaging operations to the site. We will continue to enhance our production capabilities and transfer additional production to the Dorado site.

We completed the customization and equipment installation of the new research and development facility in Dublin, Ireland with all operations transitioned and the site becoming fully operational in 2003. The previously leased site is currently in the process of being marketed for sublease.

In 2003, we leased a new facility in Bridgewater, New Jersey for our U.S. sales and marketing operation and certain clinical and management research and development operations. The facility was renovated to meet our specifications and all operations were transitioned to the new site. The previously leased site in Morrisville, North Carolina has been closed and is in the process of being marketed for sublease.

We believe our facilities are in satisfactory condition and are suitable for their intended use. We plan to invest between \$50 million and \$75 million to improve and expand our manufacturing and other related facilities over the next 24 month period. A portion of our pharmaceutical manufacturing capacity as well as other critical business functions are located in areas subject to hurricane and earthquake casualty risks. Although we have certain limited protection afforded by insurance, our business and our earnings could be materially adversely affected in the event of a major windstorm or earthquake.

We believe that we have sufficient facilities to conduct our operations during 2004. However, we continue to evaluate the purchase or lease additional properties, as our business requires.

The following table lists the location, use, size and ownership interest of our principal properties:

Location	Use	Size	Ownership
Mississauga, Ontario, Canada	Corporate office, sales, marketing and administration	55,000 Sq. Ft.	Owned
Mississauga, Ontario, Canada	Research and development	24,300 Sq. Ft.	Leased
Toronto, Ontario, Canada	Contract research and development	40,000 Sq. Ft.	Owned
Steinbach, Manitoba, Canada	Manufacturing	11,000 Sq. Ft.	Leased
Chantilly, VA, USA	Research, development	145,000 Sq. Ft.	Owned
Chantilly, VA, USA	Manufacturing, research, development, and warehousing	80,000 Sq. Ft.	Leased
Bridgewater, NJ, USA	Sales, marketing and administration	60,000 Sq. Ft.	Leased
Morrisville, NC, USA ⁽¹⁾	Sales, marketing and administration	110,000 Sq. Ft.	Leased
Dorado, Puerto Rico	Manufacturing	42,000 Sq. Ft.	Leased
Carolina, Puerto Rico	Manufacturing	120,000 Sq. Ft.	Owned
Carolina, Puerto Rico	Warehousing	34,000 Sq. Ft.	Owned
St. Michael, Barbados	Development, licensing and administration	11,200 Sq. Ft.	Leased
Christ Church, Barbados	Vacant Land	5,000 Sq. Ft.	Leased
Dublin, Ireland ⁽¹⁾	Research and development	1.8 acres	Owned
Dublin, Ireland	Research and development	5,700 Sq. Ft.	Leased
Dublin, Ireland	Research and development	27,000 Sq. Ft.	Owned

(1) Leased facilities have been vacated and are on the market to be sub leased

For additional discussion regarding our property, plant, and equipment see Item 4.B "Manufacturing Facilities".

Item 5. Operating and Financial Review and Prospects

- A. **Operating Results**
- B. **Liquidity and Capital Resources**
- C. **Research and Development, Patents and Licenses**
- D. **Trend Information**
- E. **Off-Balance Sheet Arrangements**
- F. **Tabular Disclosure of Contractual Obligations**
- G. **Safe Harbor**

**BIOVAIL CORPORATION
MANAGEMENT'S DISCUSSION AND ANALYSIS OF
FINANCIAL CONDITION AND RESULTS OF OPERATIONS
INDEX**

The following MD&A of Financial Condition and Results of Operations ("**MD&A**") prepared in accordance with U.S. GAAP should be read in conjunction with the audited consolidated financial statements and related notes thereto prepared in accordance with U.S. GAAP included under Item 18 "Financial Statements". Likewise, the following MD&A prepared in accordance with Canadian GAAP should be read in conjunction with the audited consolidated financial statements and related notes thereto prepared in accordance with Canadian GAAP also included under Item 18.

	Page
Management's Discussion and Analysis of Financial Condition and Results of Operations	
In accordance with U.S. generally accepted accounting principles	41
In accordance with Canadian generally accepted accounting principles	70

BIOVAIL CORPORATION
MANAGEMENT'S DISCUSSION AND ANALYSIS
OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

In accordance with U.S. generally accepted accounting principles
(All dollar amounts expressed in U.S. dollars)

The following Management's Discussion and Analysis of Financial Condition and Results of Operations ("MD&A") prepared in accordance with U.S. generally accepted accounting principles ("GAAP") should be read in conjunction with the audited consolidated financial statements and related notes thereto prepared in accordance with U.S. GAAP.

The discussion and analysis contained in this MD&A are as of April 23, 2004.

FORWARD-LOOKING STATEMENTS

To the extent any statements made in this report contain information that is not historical, these statements are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. We have based these forward-looking statements on our current expectations and projections about future events. Our actual results could differ materially from those discussed in, or implied by, these forward-looking statements. Forward-looking statements are identified by words such as "believe", "anticipate", "expect", "intend", "plan", "will", "may" and other similar expressions. In addition, any statements that refer to expectations, projections or other characterizations of future events or circumstances are forward-looking statements. These forward-looking statements are subject to various risks and uncertainties including, but are not necessarily limited to, the difficulty of predicting U.S. Food and Drug Administration ("FDA") and Canadian Therapeutic Products Directorate approvals, acceptance and demand for new pharmaceutical products, the impact of competitive products and pricing, new product development and launch, reliance on key strategic alliances, availability of raw materials and finished products, third parties, the regulatory environment, fluctuations in operating results and other risks detailed from time to time in our filings with the U.S. Securities and Exchange Commission ("SEC"), the Ontario Securities Commission, and other securities regulatory authorities in Canada.

PROFILE

We are a full-service pharmaceutical company, engaged in the formulation, clinical testing, registration, manufacture, promotion and sale of pharmaceutical products utilizing advanced oral drug delivery technologies. Our main therapeutic areas of focus are cardiovascular (including Type II diabetes), central nervous system and pain management.

We have various research and development, clinical testing, manufacturing, and commercial operations located in the United States, Canada, Barbados, Puerto Rico and Ireland.

OVERVIEW

2003 was a pivotal transition year for us as we moved from being primarily a developer of once-daily pharmaceutical formulations with a Canadian commercial operation towards becoming a fully integrated pharmaceutical company with expanding commercial operations in both Canada and the United States.

The highlights of 2003 were the introductions of the following products in the United States:

In September 2003, GlaxoSmithKline plc ("GSK") launched Wellbutrin XL, our once-daily formulation of bupropion hydrochloride ("HCl"), prescribed for the treatment of depression. We are the exclusive manufacturer and supplier of Wellbutrin XL to GSK. By April 2004, Wellbutrin XL accounted for approximately 40% of Wellbutrin® (including generics) prescriptions in the United States.

In July 2003, we launched Zovirax Cream, prescribed for the treatment of cold sores.

In April 2003, we launched Cardizem® LA, our graded extended-release formulation of diltiazem HCl, prescribed for the treatment of hypertension. By April 2004, Cardizem® LA accounted for approximately 10% of once-daily diltiazem formulation prescriptions in the United States.

In April 2003, we launched Teveten® HCT, prescribed for the treatment of hypertension.

We launched Zovirax Cream, Cardizem® LA and Teveten® HCT through our own commercial operations in collaboration with our co-promotion partner. Since January 1, 2004, we have been promoting these products, together with Zovirax Ointment and Teveten®, exclusively through our own commercial operations.

In 2003, we continued to make significant progress in the area of product approvals. We received New Drug Application ("NDA") approvals from the FDA for Cardizem® LA and, in collaboration with GSK, for Wellbutrin XL. This progress has continued into 2004. In February 2004, our NDA submission for Ralivia ER (tramadol HCl), for the treatment of moderate to moderately severe pain, was accepted for review by the FDA. In March 2004, we complemented this filing with a NDA submission for Ralivia FlashDose®, an oral disintegrating tablet formulation. In April 2004, we received FDA approval for our supplemental NDA for an angina indication for Cardizem® LA.

In 2003, we expanded and realigned our commercial operations in the United States, and we accommodated certain senior personnel from our commercial and research and development operations in our new 110,000 square foot facility in Bridgewater, New Jersey. We also expanded our manufacturing facility in Steinbach, Manitoba by 40,000 square feet to meet demand for the launches of Wellbutrin XL and Cardizem® LA, and we added 10 new developmental programs to our research and development pipeline. In 2004, we are adding two specialty sales forces to our U.S. commercial operations. The first will focus on cardiologists and nephrologists to promote Cardizem® LA, Teveten® and Teveten® HCT, and the second will target dermatologists, obstetrician-gynecologists and other specialists to promote Zovirax Ointment and Zovirax Cream.

Notwithstanding our successes with new product launches, the strategic investments we made in our commercial, manufacturing, and research and development operations translated into lower than anticipated earnings in 2003. We expect to continue to make significant investments in 2004 to strengthen and expand our sales and marketing infrastructure, to further increase our manufacturing capacity and efficiency, and to pursue the development of our pipeline of products. These investments are likely to limit our earnings growth in 2004; however, we believe that these investments will create substantial value for our shareholders in years subsequent to 2004, through increased revenue from our existing and pipeline products.

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

Critical accounting policies and estimates are those policies and estimates that are most important and material to the preparation of our consolidated financial statements, and which require management's most subjective and complex judgment due to the need to select policies from among alternatives available, and to make estimates about matters that are inherently uncertain. We base our estimates on historical experience and other factors that we believe to be reasonable under the circumstances. Under certain agreements, we rely on estimates and assumptions made by our third party licensees. On an ongoing basis, we review our estimates to ensure that these estimates appropriately reflect changes in our business and new information as it becomes available. If historical experience and other factors we use to make these estimates do not reasonably reflect future activity, our financial position and results of operations could be materially impacted.

Our critical accounting policies and estimates relate to the following: (i) the impact of product returns, recalls, rebates and chargebacks on revenue recognition; (ii) the valuation of acquired research and development; (iii) the evaluation of long-term investments for impairment; (iv) the useful lives of intangible assets and the evaluation of these assets for impairment; (v) the hedge effectiveness of derivative financial instruments; (vi) the determination of the provision for income taxes; and (vii) the outcome of legal proceedings.

Product returns, recalls, rebates and chargebacks

We recognize product sales revenue when title has transferred to the customer, provided that we have not retained any significant risks of ownership or future obligations with respect to the product sold. Revenue from product sales is recognized net of provisions for estimated returns, recalls, rebates and chargebacks. We establish these provisions concurrently with the recognition of product sales revenue. In connection with these provisions related to sales of products manufactured by us for distribution by our third party licensees, we rely on estimates and assumptions made by these licensees. Provisions for returns and recalls are estimated based on historical return and exchange levels, and third party data with respect to inventory levels in our distribution channels. Provisions for rebates and chargebacks are estimated based on historical experience, contractual sales terms with wholesalers and indirect customers, and relevant statutes with respect to governmental pricing programs. A significant change in these estimates could have a material impact on our results of operations.

Acquired research and development

The costs of assets that are purchased through asset acquisitions or business combinations for a particular research and development project are expensed as acquired research and development at the time of acquisition. The amount allocated to acquired research and development is determined by identifying those specific in-process research and development projects that we intend to continue, and for which: (i) technological feasibility had not been established at the date of acquisition; and (ii) there was no alternative future use. We classify the cost of acquired research and development as a cash outflow from investing activities because we expect to generate future income and cash flows from these assets if they can be developed into commercially successful products.

We generally engage independent valuation specialists to perform valuations of acquired research and development assets. There are several methods that can be used to determine the fair value of acquired assets. For acquired research and development, we generally use the income approach. This approach starts with a forecast of all of the estimated future cash flows. These cash flows are then adjusted to present value by applying an appropriate discount rate that reflects the risk factors associated with the cash flow streams. Some of the more significant estimates and assumptions inherent in the income approach include: (i) the expected costs to develop the acquired research and development into commercially viable products; (ii) the estimated future cash flows from the projects when completed; (iii) the timing of the future cash flows; and (iv) the discount rate used to reflect the risks inherent in the future cash flows. A change in any of these estimates and assumptions could have a material impact on our results of operations.

Long-term investments

We are required to estimate the fair value of our long-term investments in order to evaluate these investments for impairment. Certain of our investments are not publicly traded securities and, as a result, the estimation of the fair values of these investments involves a greater degree of uncertainty. For these types of investments, we determine fair value based on the estimated discounted future cash flows of the investee. Some of the more significant estimates and assumptions inherent in this methodology for determining fair value include: (i) the amount and timing of the future cash flows of the investee; and (ii) the discount rate used to reflect the risks inherent in the future cash flows. A change in any of these estimates and assumptions could produce a different fair value, which could have a material impact on our results of operations.

Intangible assets

Intangible assets acquired through asset acquisitions or business combinations are initially recorded at fair value based on an allocation of the purchase price. We often engage independent valuation specialists to perform valuations of the assets acquired. There are several methods that can be used to determine the fair

value of the assets acquired. For acquired intangible assets, we generally use the income approach. This approach starts with a forecast of all of the estimated future cash flows. These cash flows are then adjusted to present value by applying an appropriate discount rate that reflects the risk factors associated with the cash flow streams. Some of the more significant estimates and assumptions inherent in the income approach include: (i) the amount and timing of the future cash flows; and (ii) the discount rate used to reflect the risks inherent in the future cash flows.

Our intangible assets are stated at cost, less accumulated amortization generally computed using the straight-line method based on their estimated useful lives ranging from 8 years to 20 years. We amortize intangible assets on a systematic basis to reflect the pattern in which the economic benefits of the asset are consumed, if that basis can be reliably determined. Useful life is the period over which the intangible asset is expected to contribute directly or indirectly to our future cash flows. We determine the useful lives of intangible assets based on a number of factors such as legal, regulatory or contractual limitations, known technological advances, anticipated demand and the existence or absence of competition. A significant change in these factors may warrant a revision of the expected remaining useful life of an intangible asset, which could have a material impact on our results of operations.

We evaluate intangible assets annually for impairment, or more frequently if events or changes in circumstances indicate that the carrying amounts of these assets may not be recoverable. Impairment exists when the carrying amount of an asset is less than its estimated fair value. We determine fair value based on estimated discounted future cash flows. Some of the more significant estimates and assumptions inherent in this methodology for determining fair value include: (i) the amount and timing of the future cash flows; and (ii) the discount rate used to reflect the risks inherent in the future cash flows. A change in any of these estimates and assumptions could produce a different fair value, which could have a material impact on our results of operations.

Derivative financial instruments

We manage our exposure to interest rate risks through the use of derivative financial instruments. Our objective is to maintain a balance of fixed to floating interest rate exposure. We do not utilize derivative financial instruments for trading or speculative purposes. On the dates we entered into the derivative contracts, we designated the derivative financial instruments as a hedge of the fair value of an identified portion of a recognized long-term obligation. For a derivative financial instrument that is designated and qualifies as a fair value hedge, the derivative financial instrument is marked-to-market at each balance sheet date, with the gain or loss on the derivative financial instrument, and the respective offsetting loss or gain on the underlying hedged item, recognized in net income or loss. A discontinuance of fair value hedge accounting could have a material impact on our results of operations. Such a discontinuance did occur in 2003, and could occur in the future if changes in the fair value of the derivative financial instrument are not sufficiently correlated with changes in the fair value of the long-term obligation, based on the methods for testing effectiveness as outlined in our hedge documentation.

Provision for income taxes

Our provision for income taxes is subject to a number of different estimates made by management. A change in these estimates could have a material affect on the effective tax rate.

We have operations in various countries that have differing tax laws and rates. Our income tax reporting is subject to review by both domestic and foreign tax authorities. The effective tax rate may change from year to year based on the mix of income among the different jurisdictions in which we operate, changes in tax laws in these jurisdictions, changes in tax treaties between various countries in which we operate, and changes in the estimated values of deferred tax assets and liabilities.

We have recorded a valuation allowance on deferred tax assets primarily relating to operating losses, future tax depreciation and tax credit carryforwards. We have assumed that these deferred tax assets are more likely than not to remain unrealized. Significant judgment is applied to determine the appropriate amount of valuation allowance to record. Changes in the amount of the valuation allowance required could materially increase or decrease the provision for income taxes in a period.

Legal proceedings

We are required to accrue for a loss contingency with respect to legal proceedings against us if it is probable that the outcome will be unfavourable and if the amount of the loss can be reasonably estimated. Management evaluates our exposure to loss based on the progress of each legal proceeding, experience in similar proceedings and consultation with legal counsel. The ultimate outcome of any legal proceeding may be materially different from the amounts estimated, given the uncertainties inherent in complex litigation.

SELECTED ANNUAL INFORMATION

The following table provides selected information for the last three years.

	Years ended December 31		
	2003	2002	2001
	In 000s, except per share data		
Revenue	\$ 823,722	\$ 788,025	\$ 583,263
Net income (loss)	(27,265)	87,795	87,448
Basic earnings (loss) per share	\$ (0.17)	\$ 0.58	\$ 0.64
Diluted earnings (loss) per share	\$ (0.17)	\$ 0.55	\$ 0.58
Total assets	\$ 1,922,774	\$ 1,833,804	\$ 1,331,483
Long-term obligations	822,927	747,350	46,161

Total revenue was \$823.7 million in 2003 compared to \$788.0 million in 2002 and \$583.3 million in 2001. Total revenue increased by \$35.7 million or 5% in 2003 compared to 2002, and by \$204.7 million or 35% in 2002 compared to 2001. We recorded a net loss of \$27.3 million in 2003 compared to net income of \$87.8 million and \$87.4 million in 2002 and 2001, respectively. We recorded a diluted loss per share of \$0.17 in 2003 compared to diluted earnings per share of \$0.55 and \$0.58 in 2002 and 2001, respectively.

Impact of specific events on operations

Our results of operations were impacted by specific events that resulted in net charges of \$239.7 million, \$199.7 million and \$115.4 million in 2003, 2002 and 2001, respectively. These events include, but are not limited to: (i) relocation activities; (ii) asset impairments; (iii) acquisitions involving non-capitalized expenses, such as acquired research and development; and (iv) early extinguishments of obligations. We believe that the identification of these events enhances an analysis of our results of operations when comparing these results to those of a previous or subsequent period. However, it should be noted that the determination of these events

involves judgment by us. The impacts of these events on our results of operations in each year are identified in the following table.

	Years ended December 31		
	2003	2002	2001
	In 000s, except per share data		
Relocation costs	\$ 7,539	\$	\$
Write-down of assets	45,081	31,944	80,482
Acquired research and development	124,720	167,745	
Extinguishment of royalty obligation	61,348		
Foreign exchange loss on long-term obligation	13,061		
Reduction in tax contingency provision	(12,000)		
Debt conversion premiums			34,923
Total	\$ 239,749	\$ 199,689	\$ 115,405
Total per share (diluted)	\$ 1.50	\$ 1.24	\$ 0.77

STRATEGIC TRANSACTIONS

Year ended December 31, 2003

Tramadol FT products

In September 2003 (as amended in February 2004), we acquired from Ethypharm S.A. ("Ethypharm") the rights (including all relevant patents) to Ethypharm's Flashtab versions of tramadol ("Tramadol FT") and combination tramadol/acetaminophen ("Tramadol/Acetaminophen FT") for \$16.0 million. In March 2004, we filed an NDA for Tramadol FT (Ralivia FlashDose®) and we are continuing the development of Tramadol/Acetaminophen FT in collaboration with Ethypharm.

Carvedilol and eprosartan

In July 2003, we formed BNC-PHARMAPASS, LLC ("BNC-PHARMAPASS") with Pharma Pass II, LLC ("PPII") to advance the development of carvedilol (Coreg), a beta-blocker indicated for the treatment of congestive heart failure, eprosartan (Teveten®), indicated for the treatment of hypertension, and tamsulosin (Flomax), indicated for the treatment of benign prostatic hyperplasia. On the formation of BNC-PHARMAPASS, PPII contributed all of its intellectual property relating to these products, and we contributed cash in the amount of \$30.1 million. Subsequent to the date of formation, PPII reduced its interest in BNC-PHARMAPASS through a series of withdrawals of cash from BNC-PHARMAPASS. In February 2004, we acquired PPII's remaining interest in BNC-PHARMAPASS for \$5.0 million, for a total purchase price of \$35.1 million. We also agreed with PPII to terminate the development of tamsulosin, and the intellectual property related to this product was returned to PPII.

Ativan® and Isordil®

In May 2003, we acquired from Wyeth Pharmaceuticals Inc. ("Wyeth") the rights to Ativan® and Isordil® in the United States for \$163.8 million. Ativan® (lorazepam) is indicated for the management of anxiety disorders and Isordil® (isosorbide dinitrate) is indicated for the prevention of angina pectoris due to coronary artery disease. Wyeth will manufacture and supply Ativan® and Isordil® to us for three years from the date of acquisition. We also acquired a license to use certain technologies relating to Wyeth's Canadian sublingual version of Ativan® to develop new Ativan® products to be sold in the United States.

Athpharma products

In April 2003, we entered into an agreement with Athpharma Limited ("Athpharma") to acquire four cardiovascular products under development for \$44.2 million. The four products under development are Bisochron (bisoprolol), a beta-1 selective beta-blocker formulation for the treatment of hypertension, Isochron (isosorbide-5-mononitrate), a long acting nitrate formulation for the treatment of angina, and Hepacol I (pravastatin) and Hepacol II (simvastatin), two liver-selective statin formulations for the treatment of high cholesterol.

Year ended December 31, 2002

Pharma Pass

In December 2002, we acquired Pharma Pass LLC and Pharma Pass S.A. (collectively, "Pharma Pass") for \$178.7 million. Pharma Pass was a developer of advanced oral controlled-release technologies and formulations for pharmaceutical companies, including us, in the United States and Europe.

At the time of acquisition, Pharma Pass was involved in the development of approximately 20 branded and generic products. Subsequent to the date of acquisition, one of these products received FDA approval and we are continuing the development programs for the remaining products. Through this acquisition, we extinguished any future milestone or royalty obligations that we may have had to Pharma Pass resulting from the approval and successful commercialization of any of the products under development, pursuant to the research and development agreements we previously entered into with Pharma Pass.

Through this acquisition, we obtained Pharma Pass's interests in certain licensed products including Tricor (fenofibrate) and a participating interest in the gross profit on sales by a third party of generic omeprazole. We also obtained Pharma Pass's Zero Order Release System, a drug delivery technology that controls the rate of release of a drug and/or significantly enhances the systemic absorption of a drug molecule, and its oral Colonic Delivery System, a drug delivery technology designed for the targeted release of medication into the lower intestine and upper colon.

Pharma Tech

In December 2002, we acquired Pharmaceutical Technologies Corporation ("Pharma Tech") for \$22.6 million. Pharma Tech was a development-stage company engaged in the application of drug delivery technologies to the formulation and development of a portfolio of products. Pharma Tech contracted directly with third parties, including us, to conduct the contract research and development services.

At the time of acquisition, Pharma Tech was involved in a number of product development projects that were in various stages of completion and had not been submitted for approval by the FDA. Subsequent to the date of acquisition, we discontinued one of these projects but we are continuing the development programs for the remaining products. At the date of acquisition, two additional product development projects had received approvable letters from the FDA. We are continuing to work to resolve the issues raised in these letters. Through this acquisition we extinguished any future milestone or royalty obligations that we may have had to Pharma Tech resulting from the approval and successful commercialization of any of the products under development, pursuant to the research and development agreements we previously entered into with Pharma Tech.

Prior to the date of acquisition, we paid \$43.1 million to Pharma Tech to terminate its development of one of the products under development for us, as well as the associated royalties on future sales of this product if approved by the FDA. We are continuing the development program for this product.

Wellbutrin® SR and Zyban®

In December 2002, we acquired from GSK the rights to Wellbutrin® SR and Zyban® in Canada for \$72.0 million. Wellbutrin® SR is prescribed for the treatment of depression and Zyban® is administered for the treatment of nicotine addiction as an aid to smoking cessation. Both products are formulations of bupropion HCl. GSK will manufacture and supply Wellbutrin® SR and Zyban® to us for four years from the date of acquisition. In addition, we acquired the rights to market our once-daily formulation of bupropion HCl in Canada under the trade name Wellbutrin® XL subject to regulatory approval.

Vasotec® and Vaseretic®

In May 2002, we acquired from Merck & Co., Inc. ("Merck") the rights to Vasotec® and Vaseretic® in the United States for \$245.3 million. Vasotec® (enalapril) is a leading angiotensin converting enzyme inhibitor indicated for hypertension and symptomatic congestive heart failure and Vaseretic® is a fixed-dose combination of Vasotec® and a diuretic. Merck will manufacture and supply Vasotec® and Vaseretic® to us for five years from the date of acquisition. We are developing an enhanced formulation of Vasotec®, and a fixed-dose combination of Vasotec® with another active ingredient, to capitalize on the value of the acquired trademark. We also entered into a separate agreement with Merck to develop a new dosage format (utilizing our CEFORM technology) of a Merck product under development.

Teveten® and Teveten® HCT

In March 2002, we acquired from Solvay Pharmaceuticals Marketing & Licensing AG ("Solvay") the rights to Teveten® and Teveten® HCT in the United States for \$94.3 million. Teveten® (eprosartan) is an angiotensin-II receptor blocker that is indicated for use either alone or in conjunction with other antihypertensive medications and Teveten® HCT is a combination of Teveten® and a diuretic. Solvay will manufacture and supply Teveten® and Teveten HCT® to us for up to 12 years from the date of acquisition. We re-launched Teveten® in June 2002 and began to actively promote Teveten® HCT in April 2003 following receipt of FDA approval in February 2003.

Zovirax

Effective January 1, 2002, we acquired from GSK the exclusive distribution rights to Zovirax Ointment and Zovirax Cream in the United States for \$133.4 million. Zovirax is a topical anti-viral product. Zovirax Ointment is indicated for the treatment of herpes and Zovirax Cream is indicated for the treatment of cold sores. In December 2002, we agreed to pay GSK \$40.0 million to extend the term of the Zovirax distribution and supply agreement from 10 years to 20 years. We also agreed to pay GSK an aggregate amount of \$45.0 million, over four years beginning in 2004, to amend several terms of the original Zovirax distribution and supply agreement. GSK will manufacture and supply Zovirax Ointment and Zovirax Cream to us over the term of the amended Zovirax distribution and supply agreement. We received FDA approval for Zovirax Cream in January 2003 and launched this product in July 2003.

Year ended December 31, 2001

Wellbutrin XL

In October 2001, we entered into an agreement with GSK for the development and license of Wellbutrin XL and the co-promotion of GSK's sustained-release Wellbutrin SR®. We collaborated with GSK to complete the development of Wellbutrin XL and we licensed this product to GSK for sale and distribution in the United States. In addition, we co-promoted Wellbutrin SR® in the United States during the period from January 1, 2002 to March 31, 2003. GSK filed an NDA for Wellbutrin XL in August 2002 and received FDA approval for this product in August 2003. GSK has elected to develop and market Wellbutrin XL on a

worldwide basis (except in Canada, where we have retained the rights to market this product subject to regulatory approval). We will manufacture Wellbutrin XL to meet GSK's global supply requirements.

RESULTS OF OPERATIONS

YEAR ENDED DECEMBER 31, 2003 COMPARED TO 2002

REVENUE

Our revenue is derived from: (i) sales of pharmaceutical products; (ii) providing research and development services; (iii) the co-promotion of pharmaceutical products; and (iv) royalties and license fees. Product sales include sales of products developed and manufactured by us, as well as sales of proprietary and in-licensed products. Research and development revenue relates to product development activities in collaboration with third parties and pharmaceutical contract research services. Fees for co-promotion services are derived from the sale of co-promoted products developed by other companies. Royalties are derived from the sale of products we developed or acquired and from our interests in certain licensed products. License fees are derived from the license of our technologies or product rights.

The following table displays the dollar amount of each source of revenue in 2003 and 2002, the percentage of each source of revenue as compared to total revenue in the respective year, and the dollar and percentage changes in the dollar amount of each source from 2002 to 2003.

	Years ended December 31					
	2003		2002		Change	
	000s		000s		000s	
Product sales	\$ 632,898	77%	\$ 645,986	82%	\$ (13,088)	(2)%
Research and development	14,239	2	28,425	4	(14,186)	(50)
Co-promotion, royalty and licensing	176,585	21	113,614	14	62,971	55
	<u>\$ 823,722</u>	<u>100%</u>	<u>\$ 788,025</u>	<u>100%</u>	<u>\$ 35,697</u>	<u>5%</u>

Product sales

Product sales revenue comprises sales of Promoted products, Wellbutrin XL, Biovail Pharmaceuticals Canada ("BPC") products, Legacy products and Generic products. These categories are explained as follows:

Promoted products comprise Cardizem® LA, Zovirax Ointment and Cream, and Teveten® and Teveten® HCT. We promote these products directly to physicians in the United States through our own national network of integrated sales representatives.

We are the exclusive manufacturer and supplier of Wellbutrin XL trade and sample product to GSK. The supply price for Wellbutrin XL trade product is based on an increasing tiered percentage of revenue generated on GSK's net sales (after taking into consideration GSK's provisions for estimated discounts, returns, rebates and chargebacks) of this product. The supply price for Wellbutrin XL sample product is based on contractually agreed prices.

BPC products include Tiazac®, Cardizem® CD, Wellbutrin® SR, Zyban®, Monacor and Retavase. We promote most of these products directly to physicians in Canada through our own national network of integrated sales representatives.

Legacy products include Tiazac®, Cardizem® CD, Vasotec®, Vaseretic®, Ativan®, Isordil®, Cedax and Rondec. These products are sold in the United States. We do not promote Legacy products as most of these products have been genericized.

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 20-F

We manufacture and supply our Generic products to our distributor, Teva Pharmaceuticals USA, Inc. ("Teva"). The supply prices for our Generic products are based on a percentage of Teva's net selling prices (after taking into consideration Teva's provisions for estimated discounts, allowances, returns, rebates and chargebacks).

The following table displays product sales by category in 2003 and 2002, the percentage of each category as compared to total product sales in the respective year, and the dollar and percentage changes in the dollar amount of each category from 2002 to 2003.

	Years ended December 31					
	2003		2002		Change	
	000s		000s		000s	
Promoted products	\$ 172,418	27%	\$ 108,261	17%	\$ 64,157	59%
Wellbutrin XL	64,932	10			64,932	N/A
BPC products	85,197	14	32,565	5	52,632	162
Core products	322,547	51	140,826	22	181,721	129
Legacy products	208,860	33	323,626	50	(114,766)	(35)
Generic products	101,491	16	181,534	28	(80,043)	(44)
	\$ 632,898	100%	\$ 645,986	100%	\$ (13,088)	(2)%

Product sales were \$632.9 million in 2003 compared to \$646.0 million in 2002, a decrease of \$13.1 million or 2%.

Promoted product sales were \$172.4 million in 2003 compared to \$108.3 million in 2002, an increase of \$64.1 million or 59%. The increase in Promoted product sales in 2003 compared to 2002 reflected the launches of Teveten® HCT, Cardizem® LA and Zovirax Cream. In February 2003, we received FDA approval for Teveten® HCT, and we launched this product in March 2003. In February 2003, we also received FDA approval for a hypertension indication for Cardizem® LA, and we launched this product in April 2003. In January 2003, we received FDA approval for Zovirax Cream, and we launched this product in July 2003. In total, these new products contributed \$68.6 million in product sales revenue in 2003.

Wellbutrin XL revenue from sales of trade and sample product was \$64.9 million in 2003. Our Wellbutrin XL revenue in 2003 reflected a high initial proportion of lower value sample versus trade product sales, and the fact that most of our revenue from trade product sales was earned at the lowest tier of the supply price. In June 2003, GSK received an approvable letter from the FDA for Wellbutrin XL. In anticipation of receiving final approval for Wellbutrin XL in the third quarter of 2003, we began manufacturing and recognizing revenue from the sale of launch quantities of Wellbutrin XL to GSK immediately following the receipt of the approvable letter. GSK received final FDA approval for Wellbutrin XL in August 2003 and GSK launched this product in September 2003.

BPC product sales were \$85.2 million in 2003 compared to \$32.6 million in 2002, an increase of \$52.6 million or 162%. The increase in BPC product sales in 2003 compared to 2002 was due to higher Tiazac® sales, and the added contribution from Wellbutrin® SR and Zyban®, which we acquired from GSK in December 2002.

Core product sales is a subtotal that includes all products that we actively promote. Core product sales were \$322.5 million in 2003 compared to \$140.8 million in 2002, an increase of \$181.7 million or 129%. The increase in Core product sales reflected the additions of Wellbutrin XL, Cardizem® LA, Zovirax Cream and Teveten® HCT in the United States, and Wellbutrin® SR and Zyban® in Canada.

Legacy product sales were \$208.9 million in 2003 compared to \$323.6 million in 2002, a decrease of \$114.7 million or 35%. The decrease in Legacy product sales in 2003 compared to 2002 was mainly due to a decline in sales of Cardizem® CD and Tiazac® in the United States, which offset the added contribution from Ativan® and Isordil®, which we acquired from Wyeth in May 2003. Sales of Cardizem® CD were impacted by an overall decline in market share for this product, as well as the conversion from Cardizem® CD to Cardizem® LA. In addition, management determined that, based on recent trends in return and exchange levels and an anticipated increase in the conversion from Cardizem® CD to Cardizem® LA, the provision for product returns related primarily to Cardizem® CD should be increased. Accordingly, we recorded an increase in these provisions of approximately \$20.0 million in the fourth quarter of 2003. Sales of Tiazac® in the United States were impacted by the introduction of a generic version of this product by Andrx Corporation ("Andrx") in April 2003. We are entitled to receive a royalty from Andrx based on the net sales of its generic Tiazac® product. In April 2003, we launched our own generic version of Tiazac® through our licensee, Forest Laboratories Inc., to compete with Andrx's product.

Generic product sales were \$101.5 million in 2003 compared to \$181.5 million in 2002, a decrease of \$80.0 million or 44%. The decrease in Generic product sales in 2003 compared to 2002 was due to increased competition and lower pricing, as well as a reduction in inventory levels by Teva. We also determined through a third party audit that Teva had improperly deducted certain amounts in the calculation of net sales of our Generic products that resulted in lower than expected revenue. In the third quarter of 2003, Teva paid us \$8.5 million in compensation for a portion of these deductions, which we recorded as an addition to Generic product sales. We have commenced arbitration proceedings against Teva to recover our proportion of what we believe were additional improper deductions taken by Teva.

We expect our Promoted product sales to increase in 2004 compared to 2003 due to a full-year contribution from Cardizem® LA, Teveten® HCT and Zovirax Cream, as well as increased promotion of these products by our new specialty sales forces. We expect our revenue from Wellbutrin XL sales to increase in 2004 compared to 2003 due to a full-year contribution from this product, combined with the impact of an increasing tiered supply price through the year for Wellbutrin XL trade product, and an anticipated increase in the conversion from Wellbutrin SR® to Wellbutrin XL. We expect our BPC product sales to increase in 2004 compared to 2003 due to our promotion of Wellbutrin® SR and Zyban®. We expect our Legacy product sales to decline in 2004 compared to 2003 due to generic competition and an anticipated increase in the conversion from Cardizem® CD to Cardizem® LA. We expect our Generic product sales level to remain relatively unchanged in 2004 compared to 2003, as Teva's demand for inventory stabilizes, offsetting an anticipated decline due to competitive pressure on volume and pricing.

Research and development

Research and development activities generated revenue of \$14.2 million in 2003 compared to \$28.4 million in 2002, a decrease of \$14.2 million or 50%.

In 2002, research and development revenue included \$11.5 million of revenue associated with our development of Wellbutrin XL in collaboration with GSK. During 2002, we completed the development of Wellbutrin XL. In 2003 and 2002, our remaining research and development revenue was primarily generated from clinical research and laboratory testing services provided to external customers by our contract research operation.

We expect research and development revenue in 2004 to be comparable to the 2003 level.

Co-promotion, royalty and licensing

Co-promotion, royalty and licensing activities generated revenue of \$176.6 million in 2003 compared to \$113.6 million in 2002, an increase of \$63.0 million or 55%.

In the first quarter of 2003, we concluded our co-promotion, with GSK, of Wellbutrin SR® in the United States, and we earned the final quarterly increment of \$10.0 million. In 2002, we earned four quarterly increments, of \$10.0 million each, related to the co-promotion of Wellbutrin SR®. Our remaining co-promotion revenue was related to the co-promotion of H. Lundbeck A/S's Celexa in Canada, which amounted to \$33.1 million and \$21.0 million in 2003 and 2002, respectively. Effective December 31, 2003, we discontinued our promotion of Celexa in order to focus our marketing efforts on Wellbutrin® SR and Zyban® in Canada.

Royalty revenue increased in 2003 compared to 2002 due to the added contribution from our participating interest in the gross profit on sales by a third party of generic omeprazole, which amounted to \$103.0 million in 2003 as compared to \$20.3 million in 2002. We earned the final contribution from this participating interest in the first quarter of 2004.

We expect co-promotion, royalty and licensing revenue to be significantly lower in 2004 compared to 2003 due to conclusion of the contributions from our participating interest in generic omeprazole and the co-promotion of Celexa in Canada.

OPERATING EXPENSES

The following table displays the dollar amount of each operating expense item in 2003 and 2002, the percentage of each item as compared to total revenue in the respective year, and the dollar and percentage change in the dollar amount of each item from 2002 to 2003.

	Years ended December 31					
	2003		2002		Change	
	000s		000s		000s	
Cost of goods sold	\$ 139,456	17%	\$ 164,706	21%	\$ (25,250)	(15)%
Research and development	86,570	10	52,150	7	34,420	66
Selling, general and administrative	242,771	29	166,397	21	76,374	46
Amortization	140,895	17	71,499	9	69,396	97
Write-down of assets	45,081	5	31,944	4	13,137	41
Acquired research and development	124,720	15	167,745	21	(43,025)	(26)
Extinguishment of royalty obligation	61,348	7			61,348	N/A
Settlements	(34,055)	(4)			(34,055)	N/A
	<u>\$ 806,786</u>	<u>98%</u>	<u>\$ 654,441</u>	<u>83%</u>	<u>\$ 152,345</u>	<u>23%</u>

Cost of goods sold and gross margins

Cost of goods sold was \$139.5 million in 2003 compared to \$164.7 million in 2002, a decrease of \$25.2 million or 15%. Gross margins based on product sales were 78% in 2003 compared to 75% in 2002.

The decrease in cost of goods sold in 2003 compared to 2002 was mainly related to a lower Zovirax supply price. Effective October 1, 2002, we amended several terms of the original Zovirax distribution agreement with GSK, including a reduction in the supply price for this product. We have been paying the reduced supply price since October 1, 2002; however, the reduction in the supply price was subject to repayment if Wellbutrin XL was not approved by the FDA. Accordingly, prior to the second quarter of 2003, we had been deferring the value of the reduction in the supply price pending the outcome of the Wellbutrin XL approval. In June 2003, GSK

received an approvable letter from the FDA relating to Wellbutrin XL, which raised only routine matters. As a result, we believed that the likelihood of repaying the reduction in the supply price was low and, accordingly, we reversed the accrued liability for the deferred value of the reduction in the supply price. The recognition of the aggregate deferred value of \$25.5 million was recorded as a reduction to the cost of Zovirax sold in the second quarter of 2003. Also contributing to the decrease in cost of goods sold in 2003 was a recovery from Elan Corporation, plc ("Elan") of \$2.7 million related to its supply to us of generic versions of Adalat CC.

Gross margins in 2003 were favourably impacted by the reduction in the Zovirax supply price, the compensation received from Teva, the recovery from Elan, and the inclusion of Cardizem® LA, Ativan® and Isordil® in the product mix. Gross margins in 2003 were unfavourably impacted by the inclusion of Wellbutrin XL, due to a higher initial mix of sample versus trade product sales, and because most of the revenue from Wellbutrin XL trade product sales was earned at the lowest tier of the supply price.

We expect comparable gross margins in 2004 relative to 2003. The favourable impact on the gross margin in 2003 from the recognition of the deferred value of the reduction in the Zovirax supply price is expected to be compensated for in 2004 by a higher proportion of Wellbutrin XL trade versus sample product sales. We expect gross margins in the early part of 2004 to be lower than in the latter part of 2004 due to the impact of the increasing tiered supply price for Wellbutrin XL trade product, as well as efficiencies in the manufacturing of Wellbutrin XL, which are anticipated to occur through 2004.

Research and development

Research and development expenses were \$86.6 million in 2003 compared to \$52.2 million in 2002, an increase of \$34.4 million or 66%. As a percentage of total revenue, research and development expenses were 10% in 2003 compared to 7% in 2002.

Research and development expenses reflect direct spending on the development of products utilizing advanced oral drug delivery technologies. In the ordinary course of business, we enter into research and development collaborations with third parties to provide formulation and other services for our products under development. These third party developers are typically compensated through a combination of fees for service, milestone payments and/or royalty payments from future sales of the products under development.

The increase in research and development expenses in 2003 compared to 2002 reflected an increase in clinical activity to support the December 2003 NDA submission for Ralivia ER, which was accepted for review by the FDA in February 2004, and to support the June 2003 submission of a supplemental NDA for an angina indication for Cardizem® LA, which was approved by the FDA in April 2004. In addition, research and development expenses in 2003 compared to 2002 included the costs associated with a clinical experience program designed to evaluate the use of Cardizem® LA in a clinical practice setting.

Additional products under development in 2003 included once-daily formulations of metformin HCl, for the treatment of Type II diabetes, in collaboration with Depomed Inc. ("Depomed"), and clinically enhanced versions of venlafaxine, fenofibrate, acyclovir, simvastatin, sumatriptan and lorazepam, as well as the four cardiovascular products being developed by us in collaboration with Athpharma. In the first quarter of 2003, we evaluated the results of a Phase III clinical trial involving buspirone, for the treatment of depression, and decided to discontinue the development of this product in light of the unsatisfactory results from this trial.

We expect research and development expenses to increase in absolute dollars in 2004 compared to 2003 due to an anticipated increase in clinical activity. Our future level of research and development expenditures will depend on, among other things, the outcome of clinical testing of our products under development, delays or changes in government required testing and approval procedures, technological and competitive developments, and strategic marketing decisions.

Selling, general and administrative

Selling, general and administrative expenses were \$242.8 million in 2003 compared to \$166.4 million in 2002, an increase of \$76.4 million or 46%. As a percentage of total revenue, selling, general and administrative expenses were 29% in 2003 compared to 21% in 2002.

The increases in selling, general and administrative expenses in 2003 compared to 2002 reflected an increase in costs associated with the expansion of our commercial operations in the United States. In addition, selling, general and administrative expenses in 2003 included relocation costs of \$7.5 million associated with the transition of our commercial operations head office from Raleigh, North Carolina, as well as certain research and development personnel from Chantilly, Virginia, to our new facility in Bridgewater, New Jersey. This transition was substantially complete by December 31, 2003 and, consequently, we do not expect to incur any additional material costs related to this relocation in 2004.

Also contributing to the increases in selling, general and administrative expenses were advertising and promotional expenses related to the launches of Cardizem® LA, Teveten® HCT and Zovirax Cream. All previously deferred advertising costs at December 31, 2002, primarily related to Cardizem® LA, were expensed on the launch of this product in April 2003. Sales and marketing costs were recorded net of a \$10.0 million marketing allowance paid by Solvay in each of 2003 and 2002 to reimburse us for agreed upon direct costs to support the re-launch of Teveten® and Teveten® HCT.

In 2003 and 2002, selling, general and administrative expenses included co-promotion fees payable to Reliant Pharmaceuticals, LLC ("Reliant"). In November 2001, we entered into a co-promotion agreement with Reliant to co-promote certain of our products. Effective April 1, 2003, we amended certain terms of this agreement such that Reliant was responsible for its proportionate share of advertising and promotion costs incurred during 2003 related to the co-promoted products. Accordingly, selling, general and administrative expenses in the second and third quarters of 2003 were recorded net of an aggregate reimbursement of \$25.0 million paid by Reliant. As a result, we were able to increase the level of spending on advertising and promotion related to the co-promoted products during 2003. The terms of the amended co-promotion agreement also increased Reliant's interest in the net sales of the co-promoted products, which resulted in incremental co-promotion fees of approximately \$5.5 million. Effective December 31, 2003, we mutually agreed with Reliant to terminate this agreement (as described below under extinguishment of royalty obligation).

We expect selling, general and administrative expenses to increase in absolute dollars in 2004 compared to 2003 due to our continuing investment in our U.S. commercial operations, as well as higher sales and marketing costs to support our Promoted products.

Amortization

Amortization expense was \$140.9 million in 2003 compared to \$71.5 million in 2002, an increase of \$69.4 million or 97%. Amortization expense included the amortization of our participating interest in generic omeprazole, which amounted to \$70.7 million and \$13.5 million in 2003 and 2002, respectively. Amortization expense excluding the impact of generic omeprazole was \$70.2 million in 2003 compared to \$58.0 million in 2002, an increase of \$12.2 million or 21%. As a percentage of total revenue, amortization expense excluding the impact of generic omeprazole was 9% in 2003 compared to 7% in 2002.

The increase in amortization expense excluding the impact of generic omeprazole in 2003 compared to 2002 primarily reflected the incremental amortization associated with the acquired Ativan®, Isordil®, Wellbutrin® SR and Zyban® intangible assets.

We expect amortization expense in 2004 to be comparable in absolute dollars to amortization expense excluding the impact of generic omeprazole in 2003. We recorded the final amortization of our participating interest in generic omeprazole in the first quarter of 2004.

Write-down of assets

In the fourth quarter of 2003, we recorded a charge of \$45.1 million primarily related to the write-down of the net book values of the Cedax and Rondec product rights to their estimated fair values. In December 2003, as part of the transition of our U.S. commercial operations, we evaluated our future interest in our Cedax and Rondec product lines. We intend to focus our therapeutically aligned sales efforts on Cardizem® LA, Teveten® and Zovirax. Without continued promotion, the economic viability of Cedax and Rondec would be substantially lower, as these products require significant marketing and sales efforts in order to maintain market share. We evaluated the current and forecasted market shares for Cedax and Rondec and determined that these product rights had been permanently impaired.

In 2002, we recorded a charge of \$31.9 million primarily related to the write-down of the net book value of the generic Adalat CC product rights acquired from Elan, net of the corresponding obligation to Elan. In June 2002, we entered into a settlement with Elan and the U.S. Federal Trade Commission ("FTC") with respect to the introduction of generic versions of Adalat CC. As a result of this settlement, our agreements with Elan related to our in-licensing of Elan's generic versions of Adalat CC were terminated.

Acquired research and development

In 2003, we incurred a charge of \$124.7 million for acquired research and development, which comprised: (i) \$16.0 million related to our acquisition of Tramadol FT and Tramadol/Acetaminophen FT from Ethypharm; (ii) \$26.4 million related to our interest in BNC-PHARMAPASS's carvedilol, eprosartan and tamsulosin products; (iii) \$44.2 million related to our acquisition of the Athpharma products; and (iv) \$38.1 million related to our acquisition of the Ativan® products under development.

In 2002, we incurred a charge of \$167.7 million for acquired research and development, which comprised: (i) \$107.2 million related to our acquisition of Pharma Pass; and (ii) \$60.5 million related to our acquisition of Pharma Tech.

Extinguishment of royalty obligation

In December 2003, we mutually agreed with Reliant to terminate Reliant's co-promotion of our products, and we incurred a charge of \$61.3 million related to the payment to extinguish our trailing royalty obligation to Reliant.

Settlements

In the second quarter of 2003, we negotiated an overall settlement with Pfizer Inc. ("Pfizer"), Bayer AG, Bayer Corporation, Teva, Mylan Pharmaceuticals Inc. ("Mylan") and Mylan Laboratories Inc. through which all pending actions relating to generic versions of Procardia XL (Nifedical XL) and Adalat CC, including actions alleging patent infringement and antitrust breaches, were dismissed. In the second quarter of 2003, we also settled with Elan with respect to the termination of our rights to Elan's generic versions of Adalat CC. In the first quarter of 2003, we reached settlements with Eli Lilly and Company ("Lilly") with respect to Lilly's breach of contract due to its inability to supply us with Keftab, and with Mylan with respect to Mylan's breach of contract relating to its supply to us of verapamil (generic Verelan).

In 2003, in relation to the matters described above, we received settlement payments of \$34.1 million, mainly related to our lost profits on sales of Nifedical XL, Keftab and generic Verelan. We also received

payments totaling \$16.2 million, mainly related to a recovery of certain charges related to Elan's supply to us of generic versions of Adalat CC, which was recorded as a reduction to cost of goods sold, and compensation for legal and other expenses, which were recorded as a reduction to selling, general and administrative expenses, and interest income. We received an additional \$14.6 million, which was recorded as a reduction to assets related to the recoverable value of the Keftab product right and the value of the destroyed Keftab inventory.

OPERATING INCOME

We recorded operating income of \$16.9 million in 2003 compared to \$133.6 million in 2002, a decrease of \$116.7 million or 87%.

The decrease in operating income in 2003 compared to 2002 was mainly due to a modest increase in revenue that was more than offset by an increase in our investment spending on research and development, and sales and marketing activities, as well as on the expansion of our commercial operations in the United States. In addition, specific events, including relocation activities, asset impairments, acquisitions involving acquired research and development, and the extinguishment of the Reliant royalty obligation, reduced operating income by an aggregate amount of \$238.7 million in 2003 compared to \$199.7 million in 2002. These factors were partly offset by the recognition of settlement payments, which had the effect of increasing operating income by \$47.5 million in 2003, and the contribution from our participating interest in generic omeprazole.

NON-OPERATING ITEMS

Interest income and expense

Interest income was \$7.2 million in 2003 compared to \$3.6 million in 2002, an increase of \$3.6 million or 100%. Interest income included interest earned on our investment portfolio, which comprises primarily high-grade money market funds, and government and corporate debt securities, as well as interest on settlement payments.

Interest expense was \$40.4 million in 2003 compared to \$32.0 million in 2002, an increase of \$8.4 million or 26%. Interest expense mainly comprised interest on our 7⁷/₈% Senior Subordinated Notes due April 1, 2010 ("Notes"), which were issued in March 2002. In June 2002, we entered into three interest rate swaps in an aggregate notional amount of \$200.0 million, which involve the receipt of amounts based on a fixed rate of 7⁷/₈% in exchange for floating rate interest payments based on six-month London Interbank Offering Rate ("LIBOR") plus a spread. Net receipts of \$7.3 million in 2003 and \$3.3 million in 2002 relating to these swaps were recorded as a reduction to interest expense.

In 2003 and 2002, interest expense also included interest on advances under our revolving term credit facility, as well as the amortization of the discounts on obligations primarily related to the acquisitions of intangible assets, which amounted to \$6.6 million and \$5.3 million in 2003 and 2002, respectively.

Foreign exchange gain or loss

We recorded a foreign exchange loss of \$14.0 million in 2003 compared to a foreign exchange gain of \$0.7 million in 2002. The foreign exchange loss in 2003 included a \$13.1 million loss related to our Canadian dollar denominated obligation to GSK for the acquisition of the rights to Wellbutrin® SR and Zyban® in Canada, and was the result of a strengthening of the Canadian dollar relative to the U.S. dollar during 2003. We paid the final instalment related to this obligation in March 2004.

The remaining foreign exchange gains or losses in 2003 and 2002 mainly reflected the impact of foreign exchange fluctuations on our non-U.S. dollar denominated cash and cash equivalents, accounts receivable and accounts payable balances.

Other income or expense

The changes in the fair values of the interest rate swaps, as well as the offsetting changes in the fair value of the portion of our Notes being hedged (during those periods that hedge accounting is applied), are recorded in other income or expense. In 2003 and 2002, we recognized net gains of \$0.1 million and \$3.4 million, respectively, related to these changes in fair values.

In 2003, we recorded a \$1.0 million equity loss related to our investment in a venture fund that invests in early stage technologies.

Income taxes

Our low effective tax rate reflected the fact that most of our income was derived from foreign subsidiaries with lower statutory tax rates than those that apply in Canada. We recorded a recovery of income taxes of \$4.0 million in 2003 (which included a reduction in our provision for tax contingencies of \$12.0 million, due to the resolution of certain tax uncertainties and incremental tax losses in the United States), and a provision for income taxes of \$21.5 million in 2002. Our effective tax rate was affected by the availability of unrecognized tax loss carryforwards that can be used to offset taxable income in Canada and the United States, as well as losses that were incurred in the United States in 2003 due to the expansion of our commercial operations and the costs associated with the launches of new products.

Our future effective tax rate will depend on the relative profitability of our domestic and foreign operations, the statutory tax rates of the related tax jurisdictions, and the timing of the release, if any, of the valuation allowance. In 2004, we expect our effective tax rate to reflect anticipated losses from our operations in the United States due to planned investments to strengthen and expand our sales and marketing infrastructure.

YEAR ENDED DECEMBER 31, 2002 COMPARED TO 2001**REVENUE**

The following table displays the dollar amount of each source of revenue in 2002 and 2001, the percentage of each source of revenue as compared to total revenue in the respective year, and the dollar and percentage change in the dollar amount of each source from 2001 to 2002.

	Years ended December 31							
	2002		2001		Change			
	000s		000s		000s			
Product sales	\$ 645,986	82%	\$ 521,154	89%	\$ 124,832	24%		
Research and development	28,425	4	14,596	3	13,829	95		
Co-promotion, royalty and licensing	113,614	14	47,513	8	66,101	139		
	\$ 788,025	100%	\$ 583,263	100%	\$ 204,762	35%		

Product sales

The following table displays product sales by category in 2002 and 2001, the percentage of each category as compared to total product sales in the respective year, and the dollar and percentage changes in the dollar amount of each category from 2001 to 2002.

	Years ended December 31					
	2002		2001		Change	
	000s		000s		000s	
Promoted products	\$ 108,261	17%			\$ 108,261	N/A
BPC products	32,565	5	\$ 19,114	4%	13,451	70%
Core products	140,826	22	19,114	4	121,712	637
Legacy products	323,626	50	324,693	62	(1,067)	
Generic products	181,534	28	177,347	34	4,187	2
	\$ 645,986	100%	\$ 521,154	100%	\$ 124,832	24%

Product sales were \$646.0 million in 2002 compared to \$521.2 million in 2001, an increase of \$124.8 million or 24%.

The promotion of our Promoted products commenced in 2002. Promoted product sales were \$108.3 million in 2002, which comprised sales of Zovirax Ointment, which we acquired from GSK effective January 1, 2002, and Teveten®, which we acquired from Solvay in March 2002.

BPC product sales were \$32.6 million in 2002 compared to \$19.1 million in 2001, an increase of \$13.5 million or 70%. The increase in BPC product sales in 2002 compared to 2001 was due to higher Tiazac® sales.

Core product sales is a subtotal that includes all products that we actively promote. Core product sales were \$140.8 million in 2002 compared to \$19.1 million in 2001, an increase of \$121.7 million or 637%. The increase in Core product sales primarily reflected the additions of Zovirax Ointment and Teveten® in the United States, and higher Tiazac® sales in Canada.

Legacy product sales were \$323.6 million in 2002 compared to \$324.7 million in 2001, a decrease of \$1.1 million or less than 1%. In 2002, the added contribution from Vasotec® and Vaseretic®, which we acquired from Merck in May 2002, was offset by a decline in Cardizem® CD and Rondec sales.

Generic product sales were \$181.5 million in 2002 compared to \$177.3 million in 2001, an increase of \$4.2 million or 2%. The increase in Generic product sales in 2002 compared to 2001 reflected the approval and launch of our 90 mg generic version of Adalat CC in August 2002.

Research and development

Research and development activities generated revenue of \$28.4 million in 2002 compared to \$14.6 million in 2001, an increase of \$13.8 million or 95%.

In 2002, research and development revenue included \$11.5 million of revenue associated with our development of Wellbutrin XL in collaboration with GSK. During 2002, we completed the development of Wellbutrin XL. In 2002 and 2001, our remaining research and development revenue was primarily generated from clinical research and laboratory testing services provided to external customers by our contract research operation.

Co-promotion, royalty and licensing

Co-promotion, royalty and licensing activities generated revenue of \$113.6 million in 2002 compared to \$47.5 million in 2001, an increase of \$66.1 million or 139%.

In 2002, we earned four quarterly increments, of \$10.0 million each, related to our co-promotion, with GSK, of Wellbutrin SR® in the United States. Our remaining co-promotion revenue was related to the co-promotion of Celexa in Canada, which amounted to \$21.0 million and \$16.0 million in 2002 and 2001, respectively.

Royalty revenue increased in 2002 compared to 2001 due to the added contribution from our participating interest in the gross profit on sales by a third party of generic omeprazole, which amounted to \$20.3 million in 2002.

OPERATING EXPENSES

The following table displays the dollar amount of each operating expense item in 2002 and 2001, the percentage of each item as compared to total revenue in the respective year, and the dollar and percentage change in the dollar amount of each item from 2001 to 2002.

	Years ended December 31					
	2002		2001		Change	
	000s		000s		000s	
Cost of goods sold	\$ 164,706	21%	\$ 125,995	21%	\$ 38,711	31%
Research and development	52,150	7	51,017	9	1,133	2
Selling, general and administrative	166,397	21	109,028	19	57,369	53
Amortization	71,499	9	44,513	8	26,986	61
Write-down of assets	31,944	4	80,482	13	(48,538)	(60)
Acquired research and development	167,745	21			167,745	N/A
	<u>\$ 654,441</u>	<u>83%</u>	<u>\$ 411,035</u>	<u>70%</u>	<u>\$ 243,406</u>	<u>59%</u>

Cost of goods sold and gross margins

Cost of goods sold was \$164.7 million in 2002 compared to \$126.0 million in 2001, an increase of \$38.7 million or 31%. Gross margins based on product sales were 75% in 2002 compared to 76% in 2001.

The increase in cost of goods sold in 2002 compared to 2001 primarily reflected the additions of Zovirax Ointment and Teveten®. The gross margin in 2002 compared to 2001 was affected by a lower proportion of higher margin Cardizem® CD sales in the overall product mix and the additions of Zovirax Ointment and Teveten® sales, which generated lower margins relative to other of our products, offset by the inclusion of Vasotec® and Vaseretic® sales, which generated higher margins relative to other of our products.

Research and development

Research and development expenses were \$52.1 million in 2002 compared to \$51.0 million in 2001, an increase of \$1.1 million or 2%. As a percentage of total revenue, research and development expenses were 7% in 2002 compared to 9% in 2001.

In 2002, we completed the development of our once-daily formulation of bupropion HCl, which allowed GSK to file an NDA for Wellbutrin XL in August 2002. In addition, we completed a Phase III clinical trial to support the submission of a supplemental NDA for an angina indication for Cardizem® LA in June 2003, and we completed, or were in the process of completing, a number of comparative Phase IV studies involving Cardizem® LA.

Selling, general and administrative

Selling, general and administrative expenses were \$166.4 million in 2002 compared to \$109.0 million in 2001, an increase of \$57.4 million or 53%. As a percentage of total revenue, selling, general and administrative expenses were 21% in 2002 compared to 19% in 2001.

Selling, general and administrative expenses increased in 2002 compared to 2001 mainly due to the expansion of our commercial operations in the United States and the incremental sales and marketing costs associated with Zovirax Ointment and Teveten®, as well as costs associated with the co-promotion of Wellbutrin SR® in the United States. Sales and marketing costs were recorded net of a \$10.0 million marketing allowance paid by Solvay in 2002 to reimburse us for the agreed upon direct costs to support the re-launch of Teveten®. In 2002, we also expensed a portion of the costs associated with the development of the Cardizem® LA promotional program. In the fourth quarter of 2002, selling, general and administrative expenses included co-promotion fees payable to Reliant.

Amortization

Amortization expense was \$71.5 million in 2002 compared to \$44.5 million in 2001, an increase of \$27.0 million or 61%. As a percentage of total revenue, amortization expense was 9% in 2002 compared to 8% in 2001.

The increase in amortization expense in 2002 compared to 2001 reflected the amortization of our participating interest in generic omeprazole of \$13.5 million, and the incremental amortization associated with the acquired Zovirax, Teveten®, Vasotec® and Vaseretic® intangible assets. In 2002, amortization expense was reduced by the elimination of goodwill and workforce related amortization, which amounted to \$6.7 million in 2001.

Acquired research and development

In 2002, we incurred a charge of \$167.7 million for acquired research and development, which comprised: (i) \$107.2 million related to our acquisition of Pharma Pass; and (ii) \$60.5 million related to our acquisition of Pharma Tech.

Write-down of assets

In 2002, we recorded a charge of \$31.9 million primarily related to the write-down of the net book value of the generic Adalat CC product rights that we acquired from Elan, net of our corresponding obligation to Elan. In June 2002, we entered into a settlement with Elan and the FTC with respect to the introduction of generic versions of Adalat CC. As a result of this settlement, our agreements with Elan related to our in-licensing of Elan's generic versions of Adalat CC were terminated.

In 2001, we recorded a charge of \$80.5 million primarily related to the write-down of the net book values of the Keftab and Dura-Vent product rights. In March 2001, Keftab was voluntarily recalled by Lilly due to problems with this product's stability. In November 2000, the FDA requested a voluntary recall of products containing phenylpropanolamine ("PPA"). We immediately stopped shipments of our Dura-Vent products containing PPA and initiated a recall of these products from wholesalers and pharmacies. Subsequent supply interruptions resulted in a deterioration of customer awareness of Keftab and Dura-Vent, which would have required substantial promotional efforts to restore if these products were to have been re-launched. We evaluated the current and forecasted market shares for Keftab and Dura-Vent and determined that these product rights had been permanently impaired.

OPERATING INCOME

We recorded operating income of \$133.6 million in 2002 compared to \$172.2 million in 2001, a decrease of \$38.6 million or 22%.

The decrease in operating income in 2002 compared to 2001 was mainly due to an increase in our investment spending on sales and marketing activities, as well as on the expansion of our U.S. commercial operations. In addition, specific events, including asset impairments and acquisitions involving acquired research and development, reduced operating income by an aggregate amount of \$199.7 million in 2002 compared to \$80.5 million in 2001. These factors were partly offset by sales of our Promoted products, the inclusion of Wellbutrin SR® co-promotion revenue, and the contribution from our participating interest in generic omeprazole.

NON-OPERATING ITEMS

Interest income and expense

Interest income was \$3.6 million in 2002 compared to \$2.7 million in 2001, an increase of \$0.9 million or 33%. Interest income included interest earned on our investment portfolio, which comprises primarily high-grade money market funds, and government and corporate debt securities.

Interest expense was \$32.0 million in 2002 compared to \$36.2 million in 2001, a decrease of \$4.2 million or 12%. In 2002, interest expense mainly comprised interest on our Notes, which were issued in March 2002. In June 2002, we entered into three interest rate swaps in an aggregate notional amount of \$200.0 million, which involve the receipt of amounts based on a fixed rate of 7⁷/₈% in exchange for floating rate interest payments based on six-month LIBOR plus a spread. Net receipts of \$3.3 million in 2002 relating to these swaps were recorded as a reduction to interest expense.

In 2001, interest expense mainly comprised interest on our 6.75% Convertible Subordinated Preferred Equivalent Debentures due March 31, 2025 ("Debentures") prior to their surrender and redemption during the second half of 2001.

In 2002 and 2001, interest expense also included interest on advances under our revolving term credit facility, as well as the amortization of the discounts on obligations primarily related to the acquisitions of intangible assets, which amounted to \$5.3 million and \$11.0 million in 2002 and 2001, respectively.

Foreign exchange gain or loss

We recorded a foreign exchange gain of \$0.7 million in 2002 compared to a foreign exchange loss of \$1.1 million in 2001. Foreign exchange gains or losses in 2002 and 2001 mainly reflected the impact of foreign exchange fluctuations on our non-U.S. dollar denominated cash and cash equivalents, accounts receivable and accounts payable balances.

Other income or expense

The changes in the fair values of the interest rate swaps, as well as the offsetting changes in the fair value of the portion of our Notes being hedged, are recorded in other income or expense. In 2002, we recognized a net gain of \$3.4 million related to these changes from the inception of the fair value hedge in June 2002.

Debt conversion premiums

In 2001, we recorded debt conversion premiums of aggregate \$34.9 million on the surrender and redemption of the \$300.0 million aggregate principal amount of our outstanding Debentures.

Income taxes

Our low effective tax rate reflected the fact that most of our income was derived from foreign subsidiaries with lower statutory tax rates than those that apply in Canada. We recorded provisions for income taxes of \$21.5 million and \$15.3 million in 2002 and 2001, respectively. Our effective tax rate was affected by availability of unrecognized tax loss carryforwards that can be used to offset taxable income in Canada and the United States, as well as the low profitability of our operations in the United States in 2002 due to the expansion of our commercial operations and the costs associated with the launches of new products.

SUMMARY OF QUARTERLY RESULTS

	Q1^{(1),(2)}	Q2^{(1),(2)}	Q3^{(1),(2)}	Q4⁽²⁾	Full-Year⁽²⁾
In 000s, except per share data					
2003					
Revenue	\$ 191,390	\$ 217,283	\$ 215,314	\$ 199,735	\$ 823,722
Net income (loss)	57,599	(4,940)	16,114	(96,038)	(27,265)
Basic earnings (loss) per share	\$ 0.36	\$ (0.03)	\$ 0.10	\$ (0.60)	\$ (0.17)
Diluted earnings (loss) per share	\$ 0.36	\$ (0.03)	\$ 0.10	\$ (0.60)	\$ (0.17)
2002					
Revenue	\$ 155,253	\$ 185,131	\$ 208,944	\$ 238,697	\$ 788,025
Net income (loss)	53,051	62,557	74,977	(102,790)	87,795
Basic earnings (loss) per share	\$ 0.35	\$ 0.42	\$ 0.52	\$ (0.65)	\$ 0.58
Diluted earnings (loss) per share	\$ 0.32	\$ 0.39	\$ 0.49	\$ (0.65)	\$ 0.55

(1)

Restatement

During the course of the preparation of our 2003 annual consolidated financial statements, we determined that we had applied an inappropriate exchange rate to a Canadian dollar denominated long-term obligation. In December 2002, we acquired the rights, through a subsidiary whose functional currency is the U.S. dollar, to Wellbutrin® SR and Zyban® in Canada from GSK in a transaction denominated in Canadian dollars. At the date of acquisition, we recorded the acquired assets and the related long-term obligation in U.S. dollars at the exchange rate existing at that date. However, in our previously issued interim financial statements for 2003, we did not adjust the Wellbutrin® and Zyban® obligation to reflect changes in the exchange rate except for payments made on that obligation when a foreign exchange loss was recorded on the payment transactions. U.S. GAAP requires that monetary balances denominated in a currency other than an entity's functional currency be translated to reflect the exchange rates in existence at each balance sheet date. Consequently, the impact of the translation of the Wellbutrin® and Zyban® obligation, using the exchange rates existing at March 31, 2003, June 30, 2003 and September 30, 2003, on our previously reported interim results of operations in 2003 is summarized in the following table.

	Q1	Q2	Q3
In 000s, except per share data			
2003			
Net income (loss) as previously reported	\$ 62,991	\$ (1,012)	\$ 12,985
Foreign exchange adjustments	(5,392)	(3,928)	3,129
Net income (loss) as restated	57,599	(4,940)	16,114
Basic earnings (loss) per share			
As previously reported	\$ 0.40	\$ (0.01)	\$ 0.08
As restated	\$ 0.36	\$ (0.03)	\$ 0.10
Diluted earnings (loss) per share			
As previously reported	\$ 0.39	\$ (0.01)	\$ 0.08
As restated	\$ 0.36	\$ (0.03)	\$ 0.10

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 20-F

(2)

Impact of specific events on operations

The impacts of specific events on our interim and full-year results of operations in 2003 and 2002 are identified in the following table.

	<u>Q1</u>	<u>Q2</u>	<u>Q3</u>	<u>Q4</u>	<u>Full-Year</u>
In 000s, except per share data					
2003					
Relocation costs	\$	\$	\$ 3,156	\$ 4,383	\$ 7,539
Write-down of assets				45,081	45,081
Acquired research and development		84,200	18,409	22,111	124,720
Extinguishment of royalty obligation				61,348	61,348
Foreign exchange loss (gain) on long-term obligation	5,392	6,601	(655)	1,723	13,061
Reduction in tax contingency provision				(12,000)	(12,000)
Total	\$ 5,392	\$ 90,801	\$ 20,910	\$ 122,646	\$ 239,749
Total per share (diluted)	\$ 0.03	\$ 0.57	\$ 0.13	\$ 0.77	\$ 1.50
2002					
Write-down of assets	\$	\$	\$ 1,369	\$ 30,575	\$ 31,944
Acquired research and development				167,745	167,745
Total	\$	\$	\$ 1,369	\$ 198,320	\$ 199,689
Total per share (diluted)	\$	\$	\$ 0.01	\$ 1.25	\$ 1.24

FINANCIAL POSITION

	Years ended December 31		
	<u>2003</u>	<u>2002</u>	<u>Change</u>
In 000s			
Working capital	\$ 149,884	\$ (23,527)	\$ 173,411
Long-lived assets	1,396,776	1,432,849	(36,073)
Long-term obligations	822,927	747,350	75,577
Shareholders' equity	881,595	845,686	35,909

Working capital increased by \$173.4 million to \$149.9 million at December 31, 2003 from negative \$23.5 million at December 31, 2002. The current ratio improved to 1.6:1 at December 31, 2003 from 0.9:1 at December 31, 2002. The increase in working capital was mainly due to higher cash and cash equivalents and inventory balances, and lower current portion of long-term obligations balance. The increase in inventories was mainly due to the addition of raw material and work in process inventories of Wellbutrin XL, as well as finished goods inventories of other new products, such as Cardizem® LA, Ativan® and Isordil®. The decline in the current portion of long-term obligations reflected payments made in 2003 related to the extension of the Zovirax distribution agreement, and to the acquisition of Wellbutrin® SR and Zyban® in Canada.

Long-lived assets comprise property, plant and equipment, goodwill, intangible and other assets, net of accumulated depreciation and amortization. Long-lived assets declined by net \$36.0 million to \$1,396.8 million at December 31, 2003 from \$1,432.8 million at December 31, 2002. Capital expenditures on property, plant and equipment were \$36.9 million in 2003, which consisted mainly of additions to our manufacturing capacity to meet demand for the launches of Wellbutrin XL and Cardizem® LA. Additions to intangible assets in 2003 included the Ativan® and Isordil® trademarks, product rights and technology for \$125.7 million and an additional participating interest in generic omeprazole for \$35.5 million. Offsetting these additions to property, plant and equipment and intangible assets was depreciation and amortization of \$157.3 million, and the write-down of the Cedax and Rondec product rights of \$43.4 million, as well as the repayment of our loan

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 20-F

receivable from Reliant, coincident with the termination of our co-promotion arrangement with Reliant, which amounted to \$30.0 million at December 31, 2002.

Long-term obligations, including the current portion thereof, increased by \$75.5 million to \$822.9 million at December 31, 2003 from \$747.4 million at December 31, 2002. In 2003, we borrowed an additional \$170.0 million under our revolving term credit facility, for a total of \$280.0 million drawn at December 31, 2003, and we added a long-term obligation of \$17.5 million related to the acquisition of Ativan® and Isordil®. In 2003, we repaid \$119.3 million of long-term obligations related to the acquisitions of intangible assets.

Shareholders' equity increased by \$35.9 million to \$881.6 million at December 31, 2003 from \$845.7 million at December 31, 2002. The increase in shareholders' equity was mainly due to \$41.0 million of other comprehensive income reflecting the impact of the strengthening of the Canadian dollar relative to the U.S. dollar and an unrealized holding gain on our equity investment in Depomed, offset by the net loss of \$27.3 million recorded in 2003. The increase in shareholders' equity also reflected the issuance of \$12.1 million of common shares, mainly on the exercise of stock options, and the repayment to us of \$10.0 million of Executive Stock Purchase Plan ("ESPP") loans in 2003.

CASH FLOWS

At December 31, 2003, we had cash and cash equivalents of \$133.3 million compared to \$56.1 million at December 31, 2002 and \$434.9 million at December 31, 2001.

	Years ended December 31		
	2003	2002	2001
	In 000s		
Cash provided by operating activities	\$ 281,979	\$ 334,104	\$ 284,121
Cash used in investing activities	(278,446)	(792,467)	(57,747)
Cash provided by financing activities	72,523	79,533	83,602
Effect of exchange rate changes on cash and cash equivalents	1,125	19	(229)
	\$ 77,181	\$ (378,811)	\$ 309,747

Year ended December 31, 2003

Net cash provided by operating activities was \$282.0 million in 2003, related to the following items:

A net loss of \$27.3 million.

Adjustments for non-cash items of \$342.5 million, which included depreciation and amortization of \$157.3 million, and charges related to the write-down of assets of \$45.1 million and acquired research and development of \$124.7 million.

Net changes in non-cash operating items that reduced cash flows from operations by \$33.3 million, mainly due to an increase in inventories and a decrease in income taxes payable, partially offset by a decrease in accounts receivable.

Net cash used in investing activities was \$278.4 million in 2003, related primarily to the following items:

Acquisitions of \$242.3 million of intangible assets, which included initial cash payments of \$146.3 million for Ativan® and Isordil®, \$35.5 million related to our participating interest in generic omeprazole, \$44.2 million for the Athpharma products, and \$16.0 million for Tramadol FT and Tramadol/Acetaminophen FT.

Capital expenditures of \$36.9 million.

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 20-F

Acquisition of our interest in BNC-PHARMAPASS for \$25.7 million, net of cash acquired.

Advance to Reliant of an additional \$40.0 million, for a total loan receivable of \$70.0 million.

Repayment in cash of \$61.1 million of the loan receivable from Reliant.

Proceeds of \$10.0 million from the Lilly settlement payment related to the disposal of the Keftab product rights.

Net cash provided by financing activities was \$72.5 million in 2003, related primarily to the following items:

Borrowings of \$170.0 million under our revolving term credit facility.

Proceeds of \$12.1 million from the issue of common shares, mainly on the exercise of stock options.

Repayment to us of \$10.0 million of ESPP loans.

Repayment of \$119.3 million of long-term obligations related to the acquisitions of intangible assets.

Overall, cash and cash equivalents increased by \$77.2 million in 2003.

Year ended December 31, 2002

Net cash provided by operating activities was \$334.1 million in 2002, related to the following items:

Net income of \$87.8 million.

Adjustments for non-cash items of \$288.2 million, which included depreciation and amortization of \$82.4 million, and charges related to the write-down of assets of \$31.9 million and acquired research and development of \$167.7 million.

Net changes in non-cash operating items that reduced cash flows from operations by \$41.9 million, mainly due to an increase in accounts receivable, partially offset by increases in accounts payable and accrued liabilities.

Net cash used in investing activities was \$792.5 million in 2002, related primarily to the following items:

Acquisitions of \$375.4 million of intangible assets, which included \$133.4 million for Zovirax and \$94.3 million for Teveten®, and initial cash payments of \$145.7 million for Vasotec® and Vaseretic®.

Business acquisitions, net of cash acquired, of \$240.6 million, which comprised \$178.7 million for Pharma Pass and \$61.9 million for Pharma Tech.

Acquisitions of \$85.1 million of long-term investments, which included equity investments in Ethypharm and Depomed of \$67.8 million and \$13.7 million, respectively.

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 20-F

Capital expenditures of \$61.4 million.

Advance to Reliant of \$30.0 million.

Net cash provided by financing activities was \$79.5 million in 2002, related primarily to the following items:

Net proceeds of \$384.3 million on the issue of our Notes.

Proceeds of \$112.8 million on the exercise of warrants.

Borrowings of \$110.0 million under our revolving term credit facility.

Proceeds of \$19.6 million from the issue of common shares, mainly on the exercise of stock options.

Repurchases of \$503.1 million of our common shares on the open market, under our stock repurchase program, at an average price of \$39.08 per share.

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 20-F

Repayment of \$42.0 million of long-term obligations related to the acquisitions of intangible assets.

Overall, cash and cash equivalents decreased by \$378.8 million in 2002.

Year ended December 31, 2001

Net cash provided by operating activities was \$284.1 million in 2001, related to the following items:

Net income of \$87.4 million.

Adjustments for non-cash items of \$175.4 million, which included depreciation and amortization of \$55.3 million, and charges related to the write-down of assets of \$80.5 million and debt conversion premiums of \$23.6 million.

Net changes in non-cash operating items that increased cash flows from operations by \$21.3 million, mainly due to decreases in accounts payable and accrued liabilities, partially offset by an increase in inventories.

Net cash used in investing activities was \$57.7 million in 2001, related primarily to the following items:

Capital expenditures of \$44.4 million.

Acquisitions of \$27.4 million of intangible assets, offset by the recovery of \$15 million previously paid to Elan to license its generic versions of Adalat CC.

Net cash provided by financing activities was \$83.6 million in 2001, related primarily to the following items:

Net proceeds of \$560.0 million from our November 2001 equity offering.

Proceeds of \$29.2 million from the issue of common shares, mainly on the exercise of stock options.

Proceeds of \$29.1 million on the exercise of warrants.

Repayments of \$210.0 million under our revolving term credit facility.

Repayments \$193.4 million of long-term obligations related to the acquisitions of intangible assets.

Repurchases of \$120.0 million of our common shares on the open market, under our stock repurchase program, at an average price of \$41.79 per share.

Advance of \$10.0 million of ESPP loans.

Overall, cash and cash equivalents increased by \$309.7 million in 2001.

OFF-BALANCE SHEET ARRANGEMENTS

We did not have any off-balance sheet arrangements at December 31, 2003, other than operating leases, purchase obligations and contingent milestone payments in the normal course of business, which are reflected in the contractual obligations table below.

LIQUIDITY AND CAPITAL RESOURCES

At December 31, 2003, we had total long-term obligations of \$822.9 million, including the current portion thereof, which included the carrying value of our Notes of \$408.1 million, borrowings under our revolving term credit facility of \$280.0 million and obligations related to the acquisitions of intangible assets of \$127.8 million. At March 31, 2004, we had repaid \$80.0 million under our revolving term credit facility and \$33.1 million of obligations related to the acquisitions of intangible assets.

In March 2004, we renewed our revolving term credit facility at \$400.0 million. This facility is renewable for one-year revolving terms at the lenders' option, with a one-year term out at our option. This credit facility may

be used for general corporate purposes, including acquisitions. At December 31, 2003 and March 31, 2004, we were in compliance with all financial and non-financial covenants associated with this credit facility. At December 31, 2003 and March 31, 2004, we had advances of \$280.0 million and \$200.0 million, respectively, borrowed under this credit facility, and at each of these dates we had a letter of credit with a balance of \$61.2 million issued under this credit facility. This letter of credit secures the remaining semi-annual payments we are required to make under the Vasotec® and Vaseretic® agreement. At March 31, 2004, we had a remaining balance of \$138.8 million available to borrow under this credit facility.

The following table summarizes our fixed and contingent contractual obligations at December 31, 2003.

	Maturities by period				
	Total	Less than 1 year	1-3 years	4-5 years	After 5 years
	In 000s				
Long-term obligations	\$ 814,836	\$ 62,669	\$ 340,917	\$ 11,250	\$ 400,000
Operating lease obligations	38,200	6,400	12,000	6,200	13,600
Purchase obligation ⁽¹⁾	12,193	4,794	7,399		
Purchase obligation ⁽²⁾	21,167	N/A	N/A	N/A	N/A
Contingent milestone payments ⁽³⁾	134,785	N/A	N/A	N/A	N/A
Total contractual obligations	\$ 1,021,181	\$ 73,863	\$ 360,316	\$ 17,450	\$ 413,600

- (1) This purchase obligation is in connection with the manufacture and supply of Vasotec® and Vaseretic®. We are obligated to make semi-annual payments to Merck for minimum product quantities (regardless of the actual product supplied).
- (2) This purchase obligation is in connection with the acquisition of Ativan® and Isordil®. We will pay Wyeth a \$20.0 million additional rights payment, increasing at 10% per annum, on the approval by the FDA of the first Ativan® line extension product that may be developed by us. As this payment is contingent on receiving FDA approval of the first Ativan® line extension product, it does not have a defined maturity.
- (3) This amount comprises material contingent milestone payments in connection with certain research and development collaborations with third parties. As these payments are primarily contingent on receiving regulatory approval for the products under development, they do not have defined maturities.

In November 2003, we implemented a stock repurchase program pursuant to which we are entitled to purchase up to approximately 13.2 million of our common shares on or before November 25, 2004. Any common shares purchased by us under this program will be cancelled. To April 23, 2004, we have not repurchased any common shares under this program.

We believe that our existing balance of cash and cash equivalents, together with cash expected to be generated by our operations and existing funds available under our revolving term credit facility will be sufficient to support our operational, capital expenditure and interest requirements, as well as to meet our obligations as they become due. However, in the event that we make significant future acquisitions or change our capital structure, we may be required to raise additional funds through additional borrowings or the issuance of additional debt or equity securities.

QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are exposed to financial market risks, including changes in foreign currency exchange rates, interest rates on investments and debt obligations, and equity market prices on long-term investments. We currently use derivative financial instruments to manage our exposure to interest rate risk. We use derivative financial instruments as a risk management tool and not for trading or speculative purposes.

Inflation has not had a significant impact on our results of operations.

Foreign currency risk

We operate internationally but a majority of our revenue and expense activities and capital expenditures are denominated in U.S. dollars. Our only other significant transactions are in Canadian dollars. In 2003, we incurred a foreign exchange loss of \$13.1 million related to our Canadian dollar denominated obligation to GSK for the acquisition of the rights to Wellbutrin® SR and Zyban® in Canada. We paid the final instalment related to this obligation in March 2004 and, consequently, we do not have any material remaining non-U.S. dollar denominated obligations. A 10% change in foreign currency exchange rates would not have a material effect on our consolidated results of operations, financial position or cash flows.

Interest rate risk

The primary objective of our policy for the investment of temporary cash surpluses is the protection of principal and, accordingly, we invest in high-grade money market funds, and government and corporate securities with varying maturities, but typically less than 90 days. External independent fund administrators manage our investments. As it is our intent and policy to hold these investments until maturity, we do not have a material exposure to interest rate risk.

We are exposed to interest rate risk on borrowings under our revolving term credit facility. This credit facility bears interest based on LIBOR, U.S. dollar base rate, Canadian dollar prime rate or Canadian dollar bankers' acceptance. At our option we may lock in a rate of interest for a period of up to one year.

The imputed rates of interest used to discount our long-term obligations related to the acquisitions of intangible assets are fixed and, consequently, the fair values of these obligations are affected by changes in interest rates.

The fair value of our fixed rate Notes is affected by changes in interest rates. We manage this exposure to interest rate changes through the use of interest rate swaps, which modify our exposure to interest rate fluctuations by converting one-half of our fixed rate Notes to floating rate.

Based on our overall interest rate exposure, a 10% change in interest rates would not have a material effect on our consolidated results of operations, financial position or cash flows.

Investment risk

We are exposed to investment risks on our investments in other companies. The fair values of our investments are subject to significant fluctuations due to stock market volatility and changes in general economic conditions. We regularly review the carrying values of our investments and record losses when events and circumstances indicate that there have been other than temporary declines in their fair values.

Our initial equity investment in Ethypharm is protected in the event of any private or public financing undertaken by Ethypharm prior to June 2005. We are monitoring our investment in Ethypharm, as Ethypharm will need to achieve improvements in operating performance or a write-down of this investment may become necessary.

A 10% change in the aggregate fair values of our investments would have a material effect on our consolidated results of operations; however, it would not have a material effect on our consolidated financial position or cash flows.

RECENT ACCOUNTING PRONOUNCEMENTS

In December 2002, the Financial Accounting Standards Board ("FASB") issued Statement of Financial Accounting Standards ("SFAS") No. 148, "Accounting for Stock-Based Compensation - Transition and Disclosure". SFAS No. 148 amends SFAS No. 123 to provide alternative methods of transition to SFAS No. 123's fair value-based method of accounting for stock-based employee compensation. SFAS No. 148 also amends the disclosure provisions of SFAS No. 123 and Accounting Principles Board Opinion ("APB") No. 28, "Interim Financial Reporting", to require disclosure in the summary of significant accounting policies of the effects of an entity's accounting policy with respect to stock-based employee compensation on reported net income and earnings per share in annual and interim financial statements. SFAS No. 148 is effective for fiscal years ending after December 15, 2002. We elected to continue to use the intrinsic value-based method under the provisions of APB No. 25, "Accounting for Stock Issued to Employees", and adopted the required disclosures of SFAS No. 148 effective December 31, 2002.

In January 2003 (as amended in December 2003), the FASB issued FASB Interpretation ("FIN") No. 46, "Consolidation of Variable Interest Entities". FIN No. 46 requires consolidation of a variable interest entity ("VIE") by the primary beneficiary of the entity's expected results of operations. FIN No. 46 also requires certain disclosures by all holders of a significant variable interest in a VIE that are not the primary beneficiary. FIN No. 46 is effective immediately for VIEs created or acquired after January 31, 2003. For VIEs created or acquired prior to February 1, 2003, FIN No. 46 is effective in the first reporting period ending after December 31, 2003 for those VIEs that are considered to be special purpose entities, and after March 15, 2004 for those VIEs that are not considered to be special purpose entities. The adoption of FIN No. 46 had no effect on our financial position or results of operations.

BIOVAIL CORPORATION
MANAGEMENT'S DISCUSSION AND ANALYSIS
OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

In accordance with Canadian generally accepted accounting principles
(All dollar amounts expressed in U.S. dollars)

The following Management's Discussion and Analysis of Financial Condition and Results of Operations ("MD&A") prepared in accordance with Canadian generally accepted accounting principles ("GAAP") should be read in conjunction with the audited consolidated financial statements and related notes thereto prepared in accordance with Canadian GAAP.

The discussion and analysis contained in this MD&A are as of April 23, 2004.

FORWARD-LOOKING STATEMENTS

To the extent any statements made in this report contain information that is not historical, these statements are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. We have based these forward-looking statements on our current expectations and projections about future events. Our actual results could differ materially from those discussed in, or implied by, these forward-looking statements. Forward-looking statements are identified by words such as "believe", "anticipate", "expect", "intend", "plan", "will", "may" and other similar expressions. In addition, any statements that refer to expectations, projections or other characterizations of future events or circumstances are forward-looking statements. These forward-looking statements are subject to various risks and uncertainties including, but are not necessarily limited to, the difficulty of predicting U.S. Food and Drug Administration ("FDA") and Canadian Therapeutic Products Directorate approvals, acceptance and demand for new pharmaceutical products, the impact of competitive products and pricing, new product development and launch, reliance on key strategic alliances, availability of raw materials and finished products, third parties, the regulatory environment, fluctuations in operating results and other risks detailed from time to time in our filings with the U.S. Securities and Exchange Commission ("SEC"), the Ontario Securities Commission, and other securities regulatory authorities in Canada.

PROFILE

We are a full-service pharmaceutical company, engaged in the formulation, clinical testing, registration, manufacture, promotion and sale of pharmaceutical products utilizing advanced oral drug delivery technologies. Our main therapeutic areas of focus are cardiovascular (including Type II diabetes), central nervous system and pain management.

We have various research and development, clinical testing, manufacturing, and commercial operations located in the United States, Canada, Barbados, Puerto Rico and Ireland.

OVERVIEW

2003 was a pivotal transition year for us as we moved from being primarily a developer of once-daily pharmaceutical formulations with a Canadian commercial operation towards becoming a fully integrated pharmaceutical company with expanding commercial operations in both Canada and the United States.

The highlights of 2003 were the introductions of the following products in the United States:

In September 2003, GlaxoSmithKline plc ("GSK") launched Wellbutrin XL, our once-daily formulation of bupropion hydrochloride ("HCl"), prescribed for the treatment of depression. We are the exclusive manufacturer and supplier of Wellbutrin XL to GSK. By April 2004, Wellbutrin XL accounted for approximately 40% of Wellbutrin® (including generics) prescriptions in the United States.

In July 2003, we launched Zovirax Cream, prescribed for the treatment of cold sores.

In April 2003, we launched Cardizem® LA, our graded extended-release formulation of diltiazem HCl, prescribed for the treatment of hypertension. By April 2004, Cardizem® LA accounted for approximately 10% of once-daily diltiazem

formulation prescriptions in the United States.

In April 2003, we launched Teveten® HCT, prescribed for the treatment of hypertension.

We launched Zovirax Cream, Cardizem® LA and Teveten® HCT through our own commercial operations in collaboration with our co-promotion partner. Since January 1, 2004, we have been promoting these products, together with Zovirax Ointment and Teveten®, exclusively through our own commercial operations.

In 2003, we continued to make significant progress in the area of product approvals. We received New Drug Application ("NDA") approvals from the FDA for Cardizem® LA and, in collaboration with GSK, for Wellbutrin XL. This progress has continued into 2004. In February 2004, our NDA submission for Ralivia ER (tramadol HCl), for the treatment of moderate to moderately severe pain, was accepted for review by the FDA. In March 2004, we complemented this filing with a NDA submission for Ralivia FlashDose®, an oral disintegrating tablet formulation. In April 2004, we received FDA approval for our supplemental NDA for an angina indication for Cardizem® LA.

In 2003, we expanded and realigned our commercial operations in the United States, and we accommodated certain senior personnel from our commercial and research and development operations in our new 110,000 square foot facility in Bridgewater, New Jersey. We also expanded our manufacturing facility in Steinbach, Manitoba by 40,000 square feet to meet demand for the launches of Wellbutrin XL and Cardizem® LA, and we added 10 new developmental programs to our research and development pipeline. In 2004, we are adding two specialty sales forces to our U.S. commercial operations. The first will focus on cardiologists and nephrologists to promote Cardizem® LA, Teveten® and Teveten® HCT, and the second will target dermatologists, obstetrician-gynecologists and other specialists to promote Zovirax Ointment and Zovirax Cream.

Notwithstanding our successes with new product launches, the strategic investments we made in our commercial, manufacturing, and research and development operations translated into lower than anticipated earnings in 2003. We expect to continue to make significant investments in 2004 to strengthen and expand our sales and marketing infrastructure, to further increase our manufacturing capacity and efficiency, and to pursue the development of our pipeline of products. These investments are likely to limit our earnings growth in 2004; however, we believe that these investments will create substantial value for our shareholders in years subsequent to 2004, through increased revenue from our existing and pipeline products.

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

Critical accounting policies and estimates are those policies and estimates that are most important and material to the preparation of our consolidated financial statements, and which require management's most subjective and complex judgment due to the need to select policies from among alternatives available, and to make estimates about matters that are inherently uncertain. We base our estimates on historical experience and other factors that we believe to be reasonable under the circumstances. Under certain agreements, we rely on estimates and assumptions made by our third party licensees. On an ongoing basis, we review our estimates to ensure that these estimates appropriately reflect changes in our business and new information as it becomes available. If historical experience and other factors we use to make these estimates do not reasonably reflect future activity, our financial position and results of operations could be materially impacted.

Our critical accounting policies and estimates relate to the following: (i) the impact of product returns, recalls, rebates and chargebacks on revenue recognition; (ii) the evaluation of long-term investments for impairment; (iii) the useful lives of intangible assets (including acquired research and development) and the evaluation of these assets for impairment; (iv) the determination of the provision for income taxes; and (v) the outcome of legal proceedings.

Product returns, recalls, rebates and chargebacks

We recognize product sales revenue when title has transferred to the customer, provided that we have not retained any significant risks of ownership or future obligations with respect to the product sold. Revenue from product sales is recognized net of provisions for estimated returns, recalls, rebates and chargebacks. We establish these provisions concurrently with the recognition of product sales revenue. In connection with these provisions related to sales of products manufactured by us for distribution by our third party licensees, we rely on estimates and assumptions made by these licensees. Provisions for returns and recalls are estimated based on historical return and exchange levels, and third party data with respect to inventory levels in our distribution channels. Provisions for rebates and chargebacks are estimated based on historical experience, contractual sales terms with wholesalers and indirect customers, and relevant statutes with respect to governmental pricing programs. A significant change in these estimates could have a material impact on our results of operations.

Long-term investments

We are required to estimate the fair value of our long-term investments in order to evaluate these investments for impairment. Certain of our investments are not publicly traded securities and, as a result, the estimation of the fair values of these investments involves a greater degree of uncertainty. For these types of investments, we determine fair value based on the estimated discounted future cash flows of the investee. Some of the more significant estimates and assumptions inherent in this methodology for determining fair value include: (i) the amount and timing of the future cash flows of the investee; and (ii) the discount rate used to reflect the risks inherent in the future cash flows. A change in any of these estimates and assumptions could produce a different fair value, which could have a material impact on our results of operations.

Intangible assets

Intangible assets acquired through asset acquisitions or business combinations are initially recorded at fair value based on an allocation of the purchase price. We often engage independent valuation specialists to perform valuations of the assets acquired. There are several methods that can be used to determine the fair value of the assets acquired. For acquired intangible assets, we generally use the income approach. This approach starts with a forecast of all of the estimated future cash flows. These cash flows are then adjusted to present value by applying an appropriate discount rate that reflects the risk factors associated with the cash flow streams. Some of the more significant estimates and assumptions inherent in the income approach include: (i) the amount and timing of the future cash flows; and (ii) the discount rate used to reflect the risks inherent in the future cash flows.

The costs of assets that are purchased through asset acquisitions or business combinations for a particular research and development project are capitalized as acquired research and development at the time of acquisition. The amount allocated to acquired research and development is determined by identifying those specific in-process research and development projects that we intend to continue, and for which: (i) technological feasibility had not been established at the date of acquisition; and (ii) there was no alternative future use. We classify the cost of acquired research and development as a cash outflow from investing activities because we expect to generate future income and cash flows from these assets if they can be developed into commercially successful products.

We generally engage independent valuation specialists to perform valuations of acquired research and development assets. There are several methods that can be used to determine the fair value of acquired assets. For acquired research and development, we generally use the income approach. This approach starts with a forecast of all of the estimated future cash flows. These cash flows are then adjusted to present value by applying an appropriate discount rate that reflects the risk factors associated with the cash flow streams. Some of the more significant estimates and assumptions inherent in the income approach include: (i) the expected costs to

develop the acquired research and development into commercially viable products; (ii) the estimated future cash flows from the projects when completed; (iii) the timing of the future cash flows; and (iv) the discount rate used to reflect the risks inherent in the future cash flows. A change in any of these estimates and assumptions could have a material impact on our results of operations.

Our intangible assets are stated at cost, less accumulated amortization generally computed using the straight-line method based on their estimated useful lives ranging from 8 years to 20 years. We amortize intangible assets on a systematic basis to reflect the pattern in which the economic benefits of the asset are consumed, if that basis can be reliably determined. Useful life is the period over which the intangible asset is expected to contribute directly or indirectly to our future cash flows. We determine the useful lives of intangible assets based on a number of factors such as legal, regulatory or contractual limitations, known technological advances, anticipated demand and the existence or absence of competition. A significant change in these factors may warrant a revision of the expected remaining useful life of an intangible asset, which could have a material impact on our results of operations.

We evaluate intangible assets annually for impairment, or more frequently if events or changes in circumstances indicate that the carrying amounts of these assets may not be recoverable. Impairment exists when the carrying amount of an asset is less than its estimated fair value. We determine fair value based on estimated discounted future cash flows. Some of the more significant estimates and assumptions inherent in this methodology for determining fair value include: (i) the amount and timing of the future cash flows; and (ii) the discount rate used to reflect the risks inherent in the future cash flows. A change in any of these estimates and assumptions could produce a different fair value, which could have a material impact on our results of operations.

Provision for income taxes

Our provision for income taxes is subject to a number of different estimates made by management. A change in these estimates could have a material affect on the effective tax rate.

We have operations in various countries that have differing tax laws and rates. Our income tax reporting is subject to review by both domestic and foreign tax authorities. The effective tax rate may change from year to year based on the mix of income among the different jurisdictions in which we operate, changes in tax laws in these jurisdictions, changes in tax treaties between various countries in which we operate, and changes in the estimated values of future tax assets and liabilities.

We have recorded a valuation allowance on future tax assets primarily relating to operating losses, future tax depreciation and tax credit carryforwards. We have assumed that these future tax assets are more likely than not to remain unrealized. Significant judgment is applied to determine the appropriate amount of valuation allowance to record. Changes in the amount of the valuation allowance required could materially increase or decrease the provision for income taxes in a period.

Legal proceedings

We are required to accrue for a loss contingency with respect to legal proceedings against us if it is probable that the outcome will be unfavourable and if the amount of the loss can be reasonably estimated. Management evaluates our exposure to loss based on the progress of each legal proceeding, experience in similar proceedings and consultation with legal counsel. The ultimate outcome of any legal proceeding may be materially different from the amounts estimated, given the uncertainties inherent in complex litigation.

SELECTED ANNUAL INFORMATION

The following table provides selected information for the last three years.

(In 000s, except per share data)	Years ended December 31		
	2003	2002	2001
Revenue	\$ 823,722	\$ 788,025	\$ 583,263
Net income (loss) attributable to common shareholders	(40,345)	207,553	85,553
Basic earnings (loss) per share	\$ (0.25)	\$ 1.37	\$ 0.62
Diluted earnings (loss) per share	\$ (0.25)	\$ 1.29	\$ 0.57
Total assets	\$ 2,297,604	\$ 2,237,666	\$ 1,643,026
Long-term obligations	812,526	732,111	46,161

Total revenue was \$823.7 million in 2003 compared to \$788.0 million in 2002 and \$583.3 million in 2001. Total revenue increased by \$35.7 million or 5% in 2003 compared to 2002, and by \$204.7 million or 35% in 2002 compared to 2001. We recorded a net loss attributable to common shareholders of \$40.3 million in 2003 compared to net income attributable to common shareholders of \$207.6 million and \$85.6 million in 2002 and 2001, respectively. We recorded a diluted loss per share of \$0.25 in 2003 compared to diluted earnings per share of \$1.29 and \$0.57 in 2002 and 2001, respectively.

Impact of specific events on operations

Our results of operations were impacted by specific events that resulted in net charges of \$152.1 million, \$31.9 million and \$58.2 million in 2003, 2002 and 2001, respectively. These events include, but are not limited to: (i) relocation activities; (ii) asset impairments; and (iii) early extinguishments of obligations. We believe that the identification of these events enhances an analysis of our results of operations when comparing these results to those of a previous or subsequent period. However, it should be noted that the determination of these events involves judgment by us. The impacts of these events on our results of operations in each year are identified in the following table.

(In 000s, except per share data)	Years ended December 31		
	2003	2002	2001
Relocation costs	\$ 7,539	\$	\$
Write-down of assets, net of tax	82,189	31,944	48,246
Extinguishment of royalty obligation	61,348		
Foreign exchange loss on long-term obligation	13,061		
Reduction in tax contingency provision	(12,000)		
Debt conversion premiums			10,001
Total	\$ 152,137	\$ 31,944	\$ 58,247
Total per share (diluted)	\$ 0.95	\$ 0.20	\$ 0.39

STRATEGIC TRANSACTIONS

Year ended December 31, 2003

Tramadol FT products

In September 2003 (as amended in February 2004), we acquired from Ethypharm S.A. ("Ethypharm") the rights (including all relevant patents) to Ethypharm's Flashtab versions of tramadol ("Tramadol FT") and combination tramadol/acetaminophen ("Tramadol/Acetaminophen FT") for \$16.0 million. In March 2004, we filed an NDA for Tramadol FT (Ralivia FlashDose®) and we are continuing the development of Tramadol/Acetaminophen FT in collaboration with Ethypharm.

Carvedilol and eprosartan

In July 2003, we formed BNC-PHARMAPASS, LLC ("BNC-PHARMAPASS") with Pharma Pass II, LLC ("PPII") to advance the development of carvedilol (Coreg), a beta-blocker indicated for the treatment of congestive heart failure, eprosartan (Teveten®), indicated for the treatment of hypertension, and tamsulosin (Flomax), indicated for the treatment of benign prostatic hyperplasia. On the formation of BNC-PHARMAPASS, PPII contributed all of its intellectual property relating to these products, and we contributed cash in the amount of \$30.1 million. Subsequent to the date of formation, PPII reduced its interest in BNC-PHARMAPASS through a series of withdrawals of cash from BNC-PHARMAPASS. In February 2004, we acquired PPII's remaining interest in BNC-PHARMAPASS for \$5.0 million, for a total purchase price of \$35.1 million. We also agreed with PPII to terminate the development of tamsulosin, and the intellectual property related to this product was returned to PPII.

Ativan® and Isordil®

In May 2003, we acquired from Wyeth Pharmaceuticals Inc. ("Wyeth") the rights to Ativan® and Isordil® in the United States for \$163.8 million. Ativan® (lorazepam) is indicated for the management of anxiety disorders and Isordil® (isosorbide dinitrate) is indicated for the prevention of angina pectoris due to coronary artery disease. Wyeth will manufacture and supply Ativan® and Isordil® to us for three years from the date of acquisition. We also acquired a license to use certain technologies relating to Wyeth's Canadian sublingual version of Ativan® to develop new Ativan® products to be sold in the United States.

Athpharma products

In April 2003, we entered into an agreement with Athpharma Limited ("Athpharma") to acquire four cardiovascular products under development for \$44.2 million. The four products under development are Bisochron (bisoprolol), a beta-1 selective beta-blocker formulation for the treatment of hypertension, Isochron (isosorbide-5-mononitrate), a long acting nitrate formulation for the treatment of angina, and Hepacol I (pravastatin) and Hepacol II (simvastatin), two liver-selective statin formulations for the treatment of high cholesterol.

Year ended December 31, 2002

Pharma Pass

In December 2002, we acquired Pharma Pass LLC and Pharma Pass S.A. (collectively, "Pharma Pass") for \$178.7 million. Pharma Pass was a developer of advanced oral controlled-release technologies and formulations for pharmaceutical companies, including us, in the United States and Europe.

At the time of acquisition, Pharma Pass was involved in the development of approximately 20 branded and generic products. Subsequent to the date of acquisition, one of these products received FDA approval and we

are continuing the development programs for the remaining products. Through this acquisition, we extinguished any future milestone or royalty obligations that we may have had to Pharma Pass resulting from the approval and successful commercialization of any of the products under development, pursuant to the research and development agreements we previously entered into with Pharma Pass.

Through this acquisition, we obtained Pharma Pass's interests in certain licensed products including Tricor (fenofibrate) and a participating interest in the gross profit on sales by a third party of generic omeprazole. We also obtained Pharma Pass's Zero Order Release System, a drug delivery technology that controls the rate of release of a drug and/or significantly enhances the systemic absorption of a drug molecule, and its oral Colonic Delivery System, a drug delivery technology designed for the targeted release of medication into the lower intestine and upper colon.

Pharma Tech

In December 2002, we acquired Pharmaceutical Technologies Corporation ("Pharma Tech") for \$22.6 million. Pharma Tech was a development-stage company engaged in the application of drug delivery technologies to the formulation and development of a portfolio of products. Pharma Tech contracted directly with third parties, including us, to conduct the contract research and development services.

At the time of acquisition, Pharma Tech was involved in a number of product development projects that were in various stages of completion and had not been submitted for approval by the FDA. Subsequent to the date of acquisition, we discontinued one of these projects but we are continuing the development programs for the remaining products. At the date of acquisition, two additional product development projects had received approvable letters from the FDA. We are continuing to work to resolve the issues raised in these letters. Through this acquisition we extinguished any future milestone or royalty obligations that we may have had to Pharma Tech resulting from the approval and successful commercialization of any of the products under development, pursuant to the research and development agreements we previously entered into with Pharma Tech.

Prior to the date of acquisition, we paid \$43.1 million to Pharma Tech to terminate its development of one of the products under development for us, as well as the associated royalties on future sales of this product if approved by the FDA. We are continuing the development program for this product.

Wellbutrin® SR and Zyban®

In December 2002, we acquired from GSK the rights to Wellbutrin® SR and Zyban® in Canada for \$72.0 million. Wellbutrin® SR is prescribed for the treatment of depression and Zyban® is administered for the treatment of nicotine addiction as an aid to smoking cessation. Both products are formulations of bupropion HCl. GSK will manufacture and supply Wellbutrin® SR and Zyban® to us for four years from the date of acquisition. In addition, we acquired the rights to market our once-daily formulation of bupropion HCl in Canada under the trade name Wellbutrin® XL subject to regulatory approval.

Vasotec® and Vaseretic®

In May 2002, we acquired from Merck & Co., Inc. ("Merck") the rights to Vasotec® and Vaseretic® in the United States for \$245.3 million. Vasotec® (enalapril) is a leading angiotensin converting enzyme inhibitor indicated for hypertension and symptomatic congestive heart failure and Vaseretic® is a fixed-dose combination of Vasotec® and a diuretic. Merck will manufacture and supply Vasotec® and Vaseretic® to us for five years from the date of acquisition. We are developing an enhanced formulation of Vasotec®, and a fixed-dose combination of Vasotec® with another active ingredient, to capitalize on the value of the acquired trademark. We also entered into a separate agreement with Merck to develop a new dosage format (utilizing our CEFORM technology) of a Merck product under development.

Teveten® and Teveten® HCT

In March 2002, we acquired from Solvay Pharmaceuticals Marketing & Licensing AG ("Solvay") the rights to Teveten® and Teveten® HCT in the United States for \$94.3 million. Teveten® (eprosartan) is an angiotensin-II receptor blocker that is indicated for use either alone or in conjunction with other antihypertensive medications and Teveten® HCT is a combination of Teveten® and a diuretic. Solvay will manufacture and supply Teveten® and Teveten HCT® to us for up to 12 years from the date of acquisition. We re-launched Teveten® in June 2002 and began to actively promote Teveten® HCT in April 2003 following receipt of FDA approval in February 2003.

Zovirax

Effective January 1, 2002, we acquired from GSK the exclusive distribution rights to Zovirax Ointment and Zovirax Cream in the United States for \$133.4 million. Zovirax is a topical anti-viral product. Zovirax Ointment is indicated for the treatment of herpes and Zovirax Cream is indicated for the treatment of cold sores. In December 2002, we agreed to pay GSK \$40.0 million to extend the term of the Zovirax distribution and supply agreement from 10 years to 20 years. We also agreed to pay GSK an aggregate amount of \$45.0 million, over four years beginning in 2004, to amend several terms of the original Zovirax distribution and supply agreement. GSK will manufacture and supply Zovirax Ointment and Zovirax Cream to us over the term of the amended Zovirax distribution and supply agreement. We received FDA approval for Zovirax Cream in January 2003 and launched this product in July 2003.

Year ended December 31, 2001

Wellbutrin XL

In October 2001, we entered into an agreement with GSK for the development and license of Wellbutrin XL and the co-promotion of GSK's sustained-release Wellbutrin SR®. We collaborated with GSK to complete the development of Wellbutrin XL and we licensed this product to GSK for sale and distribution in the United States. In addition, we co-promoted Wellbutrin SR® in the United States during the period from January 1, 2002 to March 31, 2003. GSK filed an NDA for Wellbutrin XL in August 2002 and received FDA approval for this product in August 2003. GSK has elected to develop and market Wellbutrin XL on a worldwide basis (except in Canada, where we have retained the rights to market this product subject to regulatory approval). We will manufacture Wellbutrin XL to meet GSK's global supply requirements.

RESULTS OF OPERATIONS

YEAR ENDED DECEMBER 31, 2003 COMPARED TO 2002

REVENUE

Our revenue is derived from: (i) sales of pharmaceutical products; (ii) providing research and development services; (iii) the co-promotion of pharmaceutical products; and (iv) royalties and license fees. Product sales include sales of products developed and manufactured by us, as well as sales of proprietary and in-licensed products. Research and development revenue relates to product development activities in collaboration with third parties and pharmaceutical contract research services. Fees for co-promotion services are derived from the sale of co-promoted products developed by other companies. Royalties are derived from the sale of products we developed or acquired and from our interests in certain licensed products. License fees are derived from the license of our technologies or product rights.

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 20-F

The following table displays the dollar amount of each source of revenue in 2003 and 2002, the percentage of each source of revenue as compared to total revenue in the respective year, and the dollar and percentage changes in the dollar amount of each source from 2002 to 2003.

(\$ in 000s)	Years ended December 31					
	2003		2002		Change	
Product sales	\$ 632,898	77%	\$ 645,986	82%	\$ (13,088)	(2)%
Research and development	14,239	2	28,425	4	(14,186)	(50)
Co-promotion, royalty and licensing	176,585	21	113,614	14	62,971	55
	<u>\$ 823,722</u>	<u>100%</u>	<u>\$ 788,025</u>	<u>100%</u>	<u>\$ 35,697</u>	<u>5%</u>

Product sales

Product sales revenue comprises sales of Promoted products, Wellbutrin XL , Biovail Pharmaceuticals Canada ("BPC") products, Legacy products and Generic products. These categories are explained as follows:

Promoted products comprise Cardizem® LA, Zovirax Ointment and Cream, and Teveten® and Teveten® HCT. We promote these products directly to physicians in the United States through our own national network of integrated sales representatives.

We are the exclusive manufacturer and supplier of Wellbutrin XL trade and sample product to GSK. The supply price for Wellbutrin XL trade product is based on an increasing tiered percentage of revenue generated on GSK's net sales (after taking into consideration GSK's provisions for estimated discounts, returns, rebates and chargebacks) of this product. The supply price for Wellbutrin XL sample product is based on contractually agreed prices.

BPC products include Tiazac®, Cardizem® CD, Wellbutrin® SR, Zyban®, Monacor and Retavase. We promote most of these products directly to physicians in Canada through our own national network of integrated sales representatives.

Legacy products include Tiazac®, Cardizem® CD, Vasotec®, Vaseretic®, Ativan®, Isordil®, Cedax and Rondec. These products are sold in the United States. We do not promote Legacy products as most of these products have been genericized.

We manufacture and supply our Generic products to our distributor, Teva Pharmaceuticals USA, Inc. ("Teva"). The supply prices for our Generic products are based on a percentage of Teva's net selling prices (after taking into consideration Teva's provisions for estimated discounts, allowances, returns, rebates and chargebacks).

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 20-F

The following table displays product sales by category in 2003 and 2002, the percentage of each category as compared to total product sales in the respective year, and the dollar and percentage changes in the dollar amount of each category from 2002 to 2003.

(\$ in 000s)	Years ended December 31					
	2003		2002		Change	
Promoted products	\$ 172,418	27%	\$ 108,261	17%	\$ 64,157	59%
Wellbutrin XL®	64,932	10			64,932	N/A
BPC products	85,197	14	32,565	5	52,632	162
Core products	322,547	51	140,826	22	181,721	129
Legacy products	208,860	33	323,626	50	(114,766)	(35)
Generic products	101,491	16	181,534	28	(80,043)	(44)
	\$ 632,898	100%	\$ 645,986	100%	\$ (13,088)	(2)%

Product sales were \$632.9 million in 2003 compared to \$646.0 million in 2002, a decrease of \$13.1 million or 2%.

Promoted product sales were \$172.4 million in 2003 compared to \$108.3 million in 2002, an increase of \$64.1 million or 59%. The increase in Promoted product sales in 2003 compared to 2002 reflected the launches of Teveten® HCT, Cardizem® LA and Zovirax Cream. In February 2003, we received FDA approval for Teveten® HCT, and we launched this product in March 2003. In February 2003, we also received FDA approval for a hypertension indication for Cardizem® LA, and we launched this product in April 2003. In January 2003, we received FDA approval for Zovirax Cream, and we launched this product in July 2003. In total, these new products contributed \$68.6 million in product sales revenue in 2003.

Wellbutrin XL revenue from sales of trade and sample product was \$64.9 million in 2003. Our Wellbutrin XL revenue in 2003 reflected a high initial proportion of lower value sample versus trade product sales, and the fact that most of our revenue from trade product sales was earned at the lowest tier of the supply price. In June 2003, GSK received an approvable letter from the FDA for Wellbutrin XL. In anticipation of receiving final approval for Wellbutrin XL in the third quarter of 2003, we began manufacturing and recognizing revenue from the sale of launch quantities of Wellbutrin XL to GSK immediately following the receipt of the approvable letter. GSK received final FDA approval for Wellbutrin XL in August 2003 and GSK launched this product in September 2003.

BPC product sales were \$85.2 million in 2003 compared to \$32.6 million in 2002, an increase of \$52.6 million or 162%. The increase in BPC product sales in 2003 compared to 2002 was due to higher Tiazac® sales, and the added contribution from Wellbutrin® SR and Zyban®, which we acquired from GSK in December 2002.

Core product sales is a subtotal that includes all products that we actively promote. Core product sales were \$322.5 million in 2003 compared to \$140.8 million in 2002, an increase of \$181.7 million or 129%. The increase in Core product sales reflected the additions of Wellbutrin XL, Cardizem® LA, Zovirax Cream and Teveten® HCT in the United States, and Wellbutrin® SR and Zyban® in Canada.

Legacy product sales were \$208.9 million in 2003 compared to \$323.6 million in 2002, a decrease of \$114.7 million or 35%. The decrease in Legacy product sales in 2003 compared to 2002 was mainly due to a decline in sales of Cardizem® CD and Tiazac® in the United States, which offset the added contribution from Ativan® and Isordil®, which we acquired from Wyeth in May 2003. Sales of Cardizem® CD were impacted by an overall decline in market share for this product, as well as the conversion from Cardizem® CD to Cardizem® LA.

In addition, management determined that, based on recent trends in return and exchange levels and an anticipated increase in the conversion from Cardizem® CD to Cardizem® LA, the provision for product returns related primarily to Cardizem® CD should be increased. Accordingly, we recorded an increase in these provisions of approximately \$20.0 million in the fourth quarter of 2003. Sales of Tiazac® in the United States were impacted by the introduction of a generic version of this product by Andrx Corporation ("Andrx") in April 2003. We are entitled to receive a royalty from Andrx based on the net sales of its generic Tiazac® product. In April 2003, we launched our own generic version of Tiazac® through our licensee, Forest Laboratories Inc., to compete with Andrx's product.

Generic product sales were \$101.5 million in 2003 compared to \$181.5 million in 2002, a decrease of \$80.0 million or 44%. The decrease in Generic product sales in 2003 compared to 2002 was due to increased competition and lower pricing, as well as a reduction in inventory levels by Teva. We also determined through a third party audit that Teva had improperly deducted certain amounts in the calculation of net sales of our Generic products that resulted in lower than expected revenue. In the third quarter of 2003, Teva paid us \$8.5 million in compensation for a portion of these deductions, which we recorded as an addition to Generic product sales. We have commenced arbitration proceedings against Teva to recover our proportion of what we believe were additional improper deductions taken by Teva.

We expect our Promoted product sales to increase in 2004 compared to 2003 due to a full-year contribution from Cardizem® LA, Teveten® HCT and Zovirax Cream, as well as increased promotion of these products by our new specialty sales forces. We expect our revenue from Wellbutrin XL sales to increase in 2004 compared to 2003 due to a full-year contribution from this product, combined with the impact of an increasing tiered supply price through the year for Wellbutrin XL trade product, and an anticipated increase in the conversion from Wellbutrin SR® to Wellbutrin XL. We expect our BPC product sales to increase in 2004 compared to 2003 due to our promotion of Wellbutrin® SR and Zyban®. We expect our Legacy product sales to decline in 2004 compared to 2003 due to generic competition and an anticipated increase in the conversion from Cardizem® CD to Cardizem® LA. We expect our Generic product sales level to remain relatively unchanged in 2004 compared to 2003, as Teva's demand for inventory stabilizes, offsetting an anticipated decline due to competitive pressure on volume and pricing.

Research and development

Research and development activities generated revenue of \$14.2 million in 2003 compared to \$28.4 million in 2002, a decrease of \$14.2 million or 50%.

In 2002, research and development revenue included \$11.5 million of revenue associated with our development of Wellbutrin XL in collaboration with GSK. During 2002, we completed the development of Wellbutrin XL. In 2003 and 2002, our remaining research and development revenue was primarily generated from clinical research and laboratory testing services provided to external customers by our contract research operation.

We expect research and development revenue in 2004 to be comparable to the 2003 level.

Co-promotion, royalty and licensing

Co-promotion, royalty and licensing activities generated revenue of \$176.6 million in 2003 compared to \$113.6 million in 2002, an increase of \$63.0 million or 55%.

In the first quarter of 2003, we concluded our co-promotion, with GSK, of Wellbutrin SR® in the United States, and we earned the final quarterly increment of \$10.0 million. In 2002, we earned four quarterly increments, of \$10.0 million each, related to the co-promotion of Wellbutrin SR®. Our remaining co-promotion revenue was related to the co-promotion of H. Lundbeck A/S's Celexa in Canada, which amounted to

\$33.1 million and \$21.0 million in 2003 and 2002, respectively. Effective December 31, 2003, we discontinued our promotion of Celexa in order to focus our marketing efforts on Wellbutrin® SR and Zyban® in Canada.

Royalty revenue increased in 2003 compared to 2002 due to the added contribution from our participating interest in the gross profit on sales by a third party of generic omeprazole, which amounted to \$103.0 million in 2003 as compared to \$20.3 million in 2002. We earned the final contribution from this participating interest in the first quarter of 2004.

We expect co-promotion, royalty and licensing revenue to be significantly lower in 2004 compared to 2003 due to conclusion of the contributions from our participating interest in generic omeprazole and the co-promotion of Celexa in Canada.

OPERATING EXPENSES

The following table displays the dollar amount of each operating expense item in 2003 and 2002, the percentage of each item as compared to total revenue in the respective year, and the dollar and percentage change in the dollar amount of each item from 2002 to 2003.

(\$ in 000s)	Years ended December 31					
	2003		2002		Change	
Cost of goods sold	\$ 139,456	17%	\$ 164,706	21%	\$ (25,250)	(15)%
Research and development	86,570	10	52,150	7	34,420	66
Selling, general and administrative	242,771	29	166,397	21	76,374	46
Amortization	240,650	30	125,849	16	114,801	91
Write-down of assets	82,189	10	31,944	4	50,245	157
Extinguishment of royalty obligation	61,348	7			61,348	N/A
Settlements	(34,055)	(4)			(34,055)	N/A
	<u>\$ 818,929</u>	<u>99%</u>	<u>\$ 541,046</u>	<u>69%</u>	<u>\$ 277,883</u>	<u>51%</u>

Cost of goods sold and gross margins

Cost of goods sold was \$139.5 million in 2003 compared to \$164.7 million in 2002, a decrease of \$25.2 million or 15%. Gross margins based on product sales were 78% in 2003 compared to 75% in 2002.

The decrease in cost of goods sold in 2003 compared to 2002 was mainly related to a lower Zovirax supply price. Effective October 1, 2002, we amended several terms of the original Zovirax distribution agreement with GSK, including a reduction in the supply price for this product. We have been paying the reduced supply price since October 1, 2002; however, the reduction in the supply price was subject to repayment if Wellbutrin XL was not approved by the FDA. Accordingly, prior to the second quarter of 2003, we had been deferring the value of the reduction in the supply price pending the outcome of the Wellbutrin XL approval. In June 2003, GSK received an approvable letter from the FDA relating to Wellbutrin XL, which raised only routine matters. As a result, we believed that the likelihood of repaying the reduction in the supply price was low and, accordingly, we reversed the accrued liability for the deferred value of the reduction in the supply price. The recognition of the aggregate deferred value of \$25.5 million was recorded as a reduction to the cost of Zovirax sold in the second quarter of 2003. Also contributing to the decrease in cost of goods sold in 2003 was a recovery from Elan Corporation, plc ("Elan") of \$2.7 million related to its supply to us of generic versions of Adalat CC.

Gross margins in 2003 were favourably impacted by the reduction in the Zovirax supply price, the compensation received from Teva, the recovery from Elan, and the inclusion of Cardizem® LA, Ativan® and Isordil® in the product mix. Gross margins in 2003 were unfavourably impacted by the inclusion of Wellbutrin

XL, due to a higher initial mix of sample versus trade product sales, and because most of the revenue from Wellbutrin XL trade product sales was earned at the lowest tier of the supply price.

We expect comparable gross margins in 2004 relative to 2003. The favourable impact on the gross margin in 2003 from the recognition of the deferred value of the reduction in the Zovirax supply price is expected to be compensated for in 2004 by a higher proportion of Wellbutrin XL trade versus sample product sales. We expect gross margins in the early part of 2004 to be lower than in the latter part of 2004 due to the impact of the increasing tiered supply price for Wellbutrin XL trade product, as well as efficiencies in the manufacturing of Wellbutrin XL, which are anticipated to occur through 2004.

Research and development

Research and development expenses were \$86.6 million in 2003 compared to \$52.2 million in 2002, an increase of \$34.4 million or 66%. As a percentage of total revenue, research and development expenses were 10% in 2003 compared to 7% in 2002.

Research and development expenses reflect direct spending on the development of products utilizing advanced oral drug delivery technologies. In the ordinary course of business, we enter into research and development collaborations with third parties to provide formulation and other services for our products under development. These third party developers are typically compensated through a combination of fees for service, milestone payments and/or royalty payments from future sales of the products under development.

The increase in research and development expenses in 2003 compared to 2002 reflected an increase in clinical activity to support the December 2003 NDA submission for Ralivia ER, which was accepted for review by the FDA in February 2004, and to support the June 2003 submission of a supplemental NDA for an angina indication for Cardizem® LA, which was approved by the FDA in April 2004. In addition, research and development expenses in 2003 compared to 2002 included the costs associated with a clinical experience program designed to evaluate the use of Cardizem® LA in a clinical practice setting.

Additional products under development in 2003 included once-daily formulations of metformin HCl, for the treatment of Type II diabetes, in collaboration with Depomed Inc. ("Depomed"), and clinically enhanced versions of venlafaxine, fenofibrate, acyclovir, simvastatin, sumatriptan and lorazepam, as well as the four cardiovascular products being developed by us in collaboration with Athpharma. In the first quarter of 2003, we evaluated the results of a Phase III clinical trial involving buspirone, for the treatment of depression, and decided to discontinue the development of this product in light of the unsatisfactory results from this trial.

We expect research and development expenses to increase in absolute dollars in 2004 compared to 2003 due to an anticipated increase in clinical activity. Our future level of research and development expenditures will depend on, among other things, the outcome of clinical testing of our products under development, delays or changes in government required testing and approval procedures, technological and competitive developments, and strategic marketing decisions.

Selling, general and administrative

Selling, general and administrative expenses were \$242.8 million in 2003 compared to \$166.4 million in 2002, an increase of \$76.4 million or 46%. As a percentage of total revenue, selling, general and administrative expenses were 29% in 2003 compared to 21% in 2002.

The increases in selling, general and administrative expenses in 2003 compared to 2002 reflected an increase in costs associated with the expansion of our commercial operations in the United States. In addition, selling, general and administrative expenses in 2003 included relocation costs of \$7.5 million associated with the transition of our commercial operations head office from Raleigh, North Carolina, as well as certain research and development personnel from Chantilly, Virginia, to our new facility in Bridgewater, New Jersey. This

transition was substantially complete by December 31, 2003 and, consequently, we do not expect to incur any additional material costs related to this relocation in 2004.

Also contributing to the increases in selling, general and administrative expenses were advertising and promotional expenses related to the launches of Cardizem® LA, Teveten® HCT and Zovirax Cream. All previously deferred advertising costs at December 31, 2002, primarily related to Cardizem® LA, were expensed on the launch of this product in April 2003. Sales and marketing costs were recorded net of a \$10.0 million marketing allowance paid by Solvay in each of 2003 and 2002 to reimburse us for agreed upon direct costs to support the re-launch of Teveten® and Teveten® HCT.

In 2003 and 2002, selling, general and administrative expenses included co-promotion fees payable to Reliant Pharmaceuticals, LLC ("Reliant"). In November 2001, we entered into a co-promotion agreement with Reliant to co-promote certain of our products. Effective April 1, 2003, we amended certain terms of this agreement such that Reliant was responsible for its proportionate share of advertising and promotion costs incurred during 2003 related to the co-promoted products. Accordingly, selling, general and administrative expenses in the second and third quarters of 2003 were recorded net of an aggregate reimbursement of \$25.0 million paid by Reliant. As a result, we were able to increase the level of spending on advertising and promotion related to the co-promoted products during 2003. The terms of the amended co-promotion agreement also increased Reliant's interest in the net sales of the co-promoted products, which resulted in incremental co-promotion fees of approximately \$5.5 million. Effective December 31, 2003, we mutually agreed with Reliant to terminate this agreement (as described below under extinguishment of royalty obligation).

We expect selling, general and administrative expenses to increase in absolute dollars in 2004 compared to 2003 due to our continuing investment in our U.S. commercial operations, as well as higher sales and marketing costs to support our Promoted products.

Amortization

Amortization expense was \$240.7 million in 2003 compared to \$125.8 million in 2002, an increase of \$114.9 million or 91%. Amortization expense included the amortization of our participating interest in generic omeprazole, which amounted to \$70.7 million and \$13.5 million in 2003 and 2002, respectively. Amortization expense excluding the impact of generic omeprazole was \$170.0 million in 2003 compared to \$112.3 million in 2002, an increase of \$57.7 million or 51%. As a percentage of total revenue, amortization expense excluding the impact of generic omeprazole was 21% in 2003 compared to 14% in 2002.

The increase in amortization expense excluding the impact of generic omeprazole in 2003 compared to 2002 primarily reflected the incremental amortization associated with the acquired Ativan®, Isordil®, Wellbutrin® SR and Zyban® intangible assets, and with the acquired research and development related to the acquisitions of Pharma Pass and Pharma Tech.

We expect amortization expense in 2004 to increase in absolute dollars to amortization expense excluding the impact of generic omeprazole in 2003 due to the incremental amortization of acquired research and development related to the Tramadol FT, BNC-PHARMAPASS, Athpharma and Ativan® products under development. We recorded the final amortization of our participating interest in generic omeprazole in the first quarter of 2004.

Write-down of assets

In the fourth quarter of 2003, we recorded a charge of \$82.2 million related to the write-down of assets. This charge included \$49.4 million related to the write-down of the net book values of the Cedax and Rondec product rights to their estimated fair values. In December 2003, as part of the transition of our U.S. commercial operations, we evaluated our future interest in our Cedax and Rondec product lines. We intend to focus our

therapeutically aligned sales efforts on Cardizem® LA, Teveten® and Zovirax. Without continued promotion, the economic viability of Cedax and Rondec would be substantially lower, as these products require significant marketing and sales efforts in order to maintain market share. We evaluated the current and forecasted market shares for Cedax and Rondec and determined that these product rights had been permanently impaired. In addition, this charge included \$37.1 million related to the write-down of acquired research and development associated with product development projects that we have discontinued.

In 2002, we recorded a charge of \$31.9 million primarily related to the write-down of the net book value of the generic Adalat CC product rights acquired from Elan, net of the corresponding obligation to Elan. In June 2002, we entered into a settlement with Elan and the U.S. Federal Trade Commission ("FTC") with respect to the introduction of generic versions of Adalat CC. As a result of this settlement, our agreements with Elan related to our in-licensing of Elan's generic versions of Adalat CC were terminated.

Extinguishment of royalty obligation

In December 2003, we mutually agreed with Reliant to terminate Reliant's co-promotion of our products, and we incurred a charge of \$61.3 million related to the payment to extinguish our trailing royalty obligation to Reliant.

Settlements

In the second quarter of 2003, we negotiated an overall settlement with Pfizer Inc. ("Pfizer"), Bayer AG, Bayer Corporation, Teva, Mylan Pharmaceuticals Inc. ("Mylan") and Mylan Laboratories Inc. through which all pending actions relating to generic versions of Procardia XL (Nifedical XL) and Adalat CC, including actions alleging patent infringement and antitrust breaches, were dismissed. In the second quarter of 2003, we also settled with Elan with respect to the termination of our rights to Elan's generic versions of Adalat CC. In the first quarter of 2003, we reached settlements with Eli Lilly and Company ("Lilly") with respect to Lilly's breach of contract due to its inability to supply us with Keftab, and with Mylan with respect to Mylan's breach of contract relating to its supply to us of verapamil (generic Verelan).

In 2003, in relation to the matters described above, we received settlement payments of \$34.1 million, mainly related to our lost profits on sales of Nifedical XL, Keftab and generic Verelan. We also received payments totaling \$16.2 million, mainly related to a recovery of certain charges related to Elan's supply to us of generic versions of Adalat CC, which was recorded as a reduction to cost of goods sold, and compensation for legal and other expenses, which were recorded as a reduction to selling, general and administrative expenses, and interest income. We received an additional \$14.6 million, which was recorded as a reduction to assets related to the recoverable value of the Keftab product right and the value of the destroyed Keftab inventory.

OPERATING INCOME

We recorded operating income of \$4.8 million in 2003 compared to \$247.0 million in 2002, a decrease of \$242.2 million or 98%.

The decrease in operating income in 2003 compared to 2002 was mainly due to a modest increase in revenue that was more than offset by an increase in our investment spending on research and development, and sales and marketing activities, as well as on the expansion of our commercial operations in the United States. In addition, specific events, including relocation activities, asset impairments, and the extinguishment of the Reliant royalty obligation, reduced operating income by an aggregate amount of \$151.1 million in 2003 compared to \$31.9 million in 2002. These factors were partly offset by the recognition of settlement payments, which had the effect of increasing operating income by \$47.5 million in 2003, and the contribution from our participating interest in generic omeprazole.

NON-OPERATING ITEMS

Interest income and expense

Interest income was \$7.2 million in 2003 compared to \$3.6 million in 2002, an increase of \$3.6 million or 100%. Interest income included interest earned on our investment portfolio, which comprises primarily high-grade money market funds, and government and corporate debt securities, as well as interest on settlement payments.

Interest expense was \$41.3 million in 2003 compared to \$32.0 million in 2002, an increase of \$9.3 million or 29%. Interest expense mainly comprised interest on our 7⁷/₈% Senior Subordinated Notes due April 1, 2010 ("Notes"), which were issued in March 2002. In June 2002, we entered into three interest rate swaps in an aggregate notional amount of \$200.0 million, which involve the receipt of amounts based on a fixed rate of 7⁷/₈% in exchange for floating rate interest payments based on six-month London Interbank Offering Rate ("LIBOR") plus a spread. Net receipts of \$7.3 million in 2003 and \$3.3 million in 2002 relating to these swaps were recorded as a reduction to interest expense.

In 2003 and 2002, interest expense also included interest on advances under our revolving term credit facility, as well as the amortization of the discounts on obligations primarily related to the acquisitions of intangible assets, which amounted to \$7.4 million and \$5.3 million in 2003 and 2002, respectively.

Foreign exchange gain or loss

We recorded a foreign exchange loss of \$14.0 million in 2003 compared to a foreign exchange gain of \$0.7 million in 2002. The foreign exchange loss in 2003 included a \$13.1 million loss related to our Canadian dollar denominated obligation to GSK for the acquisition of the rights to Wellbutrin® SR and Zyban® in Canada, and was the result of a strengthening of the Canadian dollar relative to the U.S. dollar during 2003. We paid the final instalment related to this obligation in March 2004.

The remaining foreign exchange gains or losses in 2003 and 2002 mainly reflected the impact of foreign exchange fluctuations on our non-U.S. dollar denominated cash and cash equivalents, accounts receivable and accounts payable balances.

Other income or expense

In 2003, we recorded a \$1.0 million equity loss related to our investment in a venture fund that invests in early stage technologies.

Income taxes

Our low effective tax rate reflected the fact that most of our income was derived from foreign subsidiaries with lower statutory tax rates than those that apply in Canada. We recorded a recovery of income taxes of \$4.0 million in 2003 (which included a reduction in our provision for tax contingencies of \$12.0 million, due to the resolution of certain tax uncertainties and incremental tax losses in the United States), and a provision for income taxes of \$11.7 million in 2002 (which included a \$9.8 million recovery of future income taxes related to the reversal of temporary differences in the United States). Our effective tax rate was affected by the availability of unrecognized tax loss carryforwards that can be used to offset taxable income in Canada and the United States, as well as losses that were incurred in the United States in 2003 due to the expansion of our commercial operations and the costs associated with the launches of new products.

Our future effective tax rate will depend on the relative profitability of our domestic and foreign operations, the statutory tax rates of the related tax jurisdictions, and the timing of the release, if any, of the valuation

allowance. In 2004, we expect our effective tax rate to reflect anticipated losses from our operations in the United States due to planned investments to strengthen and expand our sales and marketing infrastructure.

YEAR ENDED DECEMBER 31, 2002 COMPARED TO 2001

REVENUE

The following table displays the dollar amount of each source of revenue in 2002 and 2001, the percentage of each source of revenue as compared to total revenue in the respective year, and the dollar and percentage change in the dollar amount of each source from 2001 to 2002.

(\$ in 000s)	Years ended December 31					
	2002		2001		Change	
Product sales	\$ 645,986	82%	\$ 521,154	89%	\$ 124,832	24%
Research and development	28,425	4	14,596	3	13,829	95
Co-promotion, royalty and licensing	113,614	14	47,513	8	66,101	139
	\$ 788,025	100%	\$ 583,263	100%	\$ 204,762	35%

Product sales

The following table displays product sales by category in 2002 and 2001, the percentage of each category as compared to total product sales in the respective year, and the dollar and percentage changes in the dollar amount of each category from 2001 to 2002.

(\$ in 000s)	Years ended December 31					
	2002		2001		Change	
Promoted products	\$ 108,261	17%			\$ 108,261	N/A
BPC products	32,565	5	19,114	4	13,451	70
Core products	140,826	22	19,114	4	121,712	637
Legacy products	323,626	50	324,693	62	(1,067)	
Generic products	181,534	28	177,347	34	4,187	2
	\$ 645,986	100%	\$ 521,154	100%	\$ 124,832	24%

Product sales were \$646.0 million in 2002 compared to \$521.2 million in 2001, an increase of \$124.8 million or 24%.

The promotion of our Promoted products commenced in 2002. Promoted product sales were \$108.3 million in 2002, which comprised sales of Zovirax Ointment, which we acquired from GSK effective January 1, 2002, and Teveten®, which we acquired from Solvay in March 2002.

BPC product sales were \$32.6 million in 2002 compared to \$19.1 million in 2001, an increase of \$13.5 million or 70%. The increase in BPC product sales in 2002 compared to 2001 was due to higher Tiazac® sales.

Core product sales is a subtotal that includes all products that we actively promote. Core product sales were \$140.8 million in 2002 compared to \$19.1 million in 2001, an increase of \$121.7 million or 637%. The increase in Core product sales primarily reflected the additions of Zovirax Ointment and Teveten® in the United States, and higher Tiazac® sales in Canada.

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 20-F

Legacy product sales were \$323.6 million in 2002 compared to \$324.7 million in 2001, a decrease of \$1.1 million or less than 1%. In 2002, the added contribution from Vasotec® and Vaseretic®, which we acquired from Merck in May 2002, was offset by a decline in Cardizem® CD and Rondec sales.

Generic product sales were \$181.5 million in 2002 compared to \$177.3 million in 2001, an increase of \$4.2 million or 2%. The increase in Generic product sales in 2002 compared to 2001 reflected the approval and launch of our 90 mg generic version of Adalat CC in August 2002.

Research and development

Research and development activities generated revenue of \$28.4 million in 2002 compared to \$14.6 million in 2001, an increase of \$13.8 million or 95%.

In 2002, research and development revenue included \$11.5 million of revenue associated with our development of Wellbutrin XL in collaboration with GSK. During 2002, we completed the development of Wellbutrin XL. In 2002 and 2001, our remaining research and development revenue was primarily generated from clinical research and laboratory testing services provided to external customers by our contract research operation.

Co-promotion, royalty and licensing

Co-promotion, royalty and licensing activities generated revenue of \$113.6 million in 2002 compared to \$47.5 million in 2001, an increase of \$66.1 million or 139%.

In 2002, we earned four quarterly increments, of \$10.0 million each, related to our co-promotion, with GSK, of Wellbutrin SR® in the United States. Our remaining co-promotion revenue was related to the co-promotion of Celexa in Canada, which amounted to \$21.0 million and \$16.0 million in 2002 and 2001, respectively.

Royalty revenue increased in 2002 compared to 2001 due to the added contribution from our participating interest in the gross profit on sales by a third party of generic omeprazole, which amounted to \$20.3 million in 2002.

OPERATING EXPENSES

The following table displays the dollar amount of each operating expense item in 2002 and 2001, the percentage of each item as compared to total revenue in the respective year, and the dollar and percentage change in the dollar amount of each item from 2001 to 2002.

(\$ in 000s)	Years ended December 31					
	2002		2001		Change	
Cost of goods sold	\$ 164,706	21%	\$ 125,995	21%	\$ 38,711	31%
Research and development	52,150	7	51,017	9	1,133	2
Selling, general and administrative	166,397	21	110,290	19	56,107	51
Amortization	125,849	16	98,097	17	27,752	28
Write-down of assets	31,944	4	80,482	13	(48,538)	(60)
	<u>\$ 541,046</u>	<u>69%</u>	<u>\$ 465,881</u>	<u>79%</u>	<u>\$ 75,165</u>	<u>16%</u>

Cost of goods sold and gross margins

Cost of goods sold was \$164.7 million in 2002 compared to \$126.0 million in 2001, an increase of \$38.7 million or 31%. Gross margins based on product sales were 75% in 2002 compared to 76% in 2001.

The increase in cost of goods sold in 2002 compared to 2001 primarily reflected the additions of Zovirax Ointment and Teveten®. The gross margin in 2002 compared to 2001 was affected by a lower proportion of higher margin Cardizem® CD sales in the overall product mix and the additions of Zovirax Ointment and Teveten® sales, which generated lower margins relative to other of our products, offset by the inclusion of Vasotec® and Vaseretic® sales, which generated higher margins relative to other of our products.

Research and development

Research and development expenses were \$52.1 million in 2002 compared to \$51.0 million in 2001, an increase of \$1.1 million or 2%. As a percentage of total revenue, research and development expenses were 7% in 2002 compared to 9% in 2001.

In 2002, we completed the development of our once-daily formulation of bupropion HCl, which allowed GSK to file an NDA for Wellbutrin XL in August 2002. In addition, we completed a Phase III clinical trial to support the submission of a supplemental NDA for an angina indication for Cardizem® LA in June 2003, and we completed, or were in the process of completing, a number of comparative Phase IV studies involving Cardizem® LA.

Selling, general and administrative

Selling, general and administrative expenses were \$166.4 million in 2002 compared to \$110.3 million in 2001, an increase of \$56.1 million or 51%. As a percentage of total revenue, selling, general and administrative expenses were 21% in 2002 compared to 19% in 2001.

Selling, general and administrative expenses increased in 2002 compared to 2001 mainly due to the expansion of our commercial operations in the United States and the incremental sales and marketing costs associated with Zovirax Ointment and Teveten®, as well as costs associated with the co-promotion of Wellbutrin SR® in the United States. Sales and marketing costs were recorded net of a \$10.0 million marketing allowance paid by Solvay in 2002 to reimburse us for the agreed upon direct costs to support the re-launch of Teveten®. In 2002, we also expensed a portion of the costs associated with the development of the Cardizem® LA promotional program. In the fourth quarter of 2002, selling, general and administrative expenses included co-promotion fees payable to Reliant.

Amortization

Amortization expense was \$125.8 million in 2002 compared to \$98.1 million in 2001, an increase of \$27.7 million or 28%. As a percentage of total revenue, amortization expense was 16% in 2002 compared to 17% in 2001.

The increase in amortization expense in 2002 compared to 2001 reflected the amortization of our participating interest in generic omeprazole of \$13.5 million, and the incremental amortization associated with the acquired Zovirax, Teveten®, Vasotec® and Vaseretic® intangible assets. In 2002, amortization expense was reduced by the elimination of goodwill and workforce related amortization, which amounted to \$6.9 million in 2001.

Write-down of assets

In 2002, we recorded a charge of \$31.9 million primarily related to the write-down of the net book value of the generic Adalat CC product rights that we acquired from Elan, net of our corresponding obligation to Elan. In June 2002, we entered into a settlement with Elan and the FTC with respect to the introduction of generic versions of Adalat CC. As a result of this settlement, our agreements with Elan related to our in-licensing of Elan's generic versions of Adalat CC were terminated.

In 2001, we recorded a charge of \$80.5 million primarily related to the write-down of the net book values of the Keftab and Dura-Vent product rights. In March 2001, Keftab was voluntarily recalled by Lilly due to problems with this product's stability. In November 2000, the FDA requested a voluntary recall of products containing phenylpropanolamine ("PPA"). We immediately stopped shipments of our Dura-Vent products containing PPA and initiated a recall of these products from wholesalers and pharmacies. Subsequent supply interruptions resulted in a deterioration of customer awareness of Keftab and Dura-Vent, which would have required substantial promotional efforts to restore if these products were to have been re-launched. We evaluated the current and forecasted market shares for Keftab and Dura-Vent and determined that these product rights had been permanently impaired.

OPERATING INCOME

We recorded operating income of \$247.0 million in 2002 compared to \$117.4 million in 2001, an increase of \$129.6 million or 110%.

The increase in operating income in 2002 compared to 2001 was mainly due to sales of our Promoted products, the inclusion of Wellbutrin SR® co-promotion revenue, and the contribution from our participating interest in generic omeprazole. These factors were partly offset by an increase in our investment spending on sales and marketing activities, as well as on the expansion of our U.S. commercial operations. In addition, asset impairments reduced operating income by an aggregate amount of \$31.9 million in 2002 compared to \$80.5 million in 2001.

NON-OPERATING ITEMS

Interest income and expense

Interest income was \$3.6 million in 2002 compared to \$2.7 million in 2001, an increase of \$0.9 million or 33%. Interest income included interest earned on our investment portfolio, which comprises primarily high-grade money market funds, and government and corporate debt securities.

Interest expense was \$32.0 million in 2002 compared to \$21.1 million in 2001, an increase of \$10.9 million or 52%. In 2002, interest expense mainly comprised interest on our Notes, which were issued in March 2002. In June 2002, we entered into three interest rate swaps in an aggregate notional amount of \$200.0 million, which involve the receipt of amounts based on a fixed rate of 7⁷/₈% in exchange for floating rate interest payments based on six-month LIBOR plus a spread. Net receipts of \$3.3 million in 2002 relating to these swaps were recorded as a reduction to interest expense.

In 2002 and 2001, interest expense also included interest on advances under our revolving term credit facility, as well as the amortization of the discounts on obligations related to the acquisitions of intangible assets, which amounted to \$5.3 million and \$11.0 million in 2002 and 2001, respectively.

Foreign exchange gain or loss

We recorded a foreign exchange gain of \$0.7 million in 2002 compared to a foreign exchange loss of \$1.1 million in 2001. Foreign exchange gains or losses in 2002 and 2001 mainly reflected the impact of foreign exchange fluctuations on our non-U.S. dollar denominated cash and cash equivalents, accounts receivable and accounts payable balances.

Income taxes

Our low effective tax rate reflected the fact that most of our income was derived from foreign subsidiaries with lower statutory tax rates than those that apply in Canada. We recorded a provision for income taxes of \$11.7 million in 2002 and a recovery of income taxes of \$26.0 million in 2001. We recorded recoveries of future

income taxes of \$9.8 million and \$39.8 million in 2002 and 2001, respectively, related to the reversal of temporary differences and the write-down of assets in the United States. Our effective tax rate was affected by availability of unrecognized tax loss carryforwards that can be used to offset taxable income in Canada and the United States, as well as the low profitability of our operations in the United States in 2002 due to the expansion of our commercial operations and the costs associated with the launches of new products.

Interest on Convertible Subordinated Preferred Equivalent Debentures

The value of our 6.75% Convertible Subordinated Preferred Equivalent Debentures due March 31, 2025 ("Debentures") was comprised of the holder conversion option and the interest and principal components. In 2001, interest on our Debentures was comprised of interest expense of \$14.9 million and the accretion of the principal and interest components of \$13.5 million.

Debt conversion premiums

In 2001, we recorded debt conversion premiums of aggregate \$34.9 million on the surrender and redemption of the \$300.0 million aggregate principal amount of our outstanding Debentures. The portions of these premiums related to the interest and principal components of our Debentures of \$10.0 million were deducted from net income for the determination of net income attributable to common shareholders, and the portions of these premiums related to the holder conversion option of \$24.9 million were charged to retained earnings.

SUMMARY OF QUARTERLY RESULTS

(In 000s, except per share data)	Q1 ^{(1),(2)}	Q2 ^{(1),(2)}	Q3 ^{(1),(2)}	Q4 ⁽²⁾	Full-Year ⁽²⁾
2003					
Revenue	\$ 191,390	\$ 217,283	\$ 215,314	\$ 199,735	\$ 823,722
Net income (loss)	35,368	49,238	13,351	(138,302)	(40,345)
Basic earnings (loss) per share	\$ 0.22	\$ 0.31	\$ 0.08	\$ (0.87)	\$ (0.25)
Diluted earnings (loss) per share	\$ 0.22	\$ 0.31	\$ 0.08	\$ (0.87)	\$ (0.25)
2002					
Revenue	\$ 155,253	\$ 185,131	\$ 208,944	\$ 238,697	\$ 788,025
Net income	40,665	50,069	59,247	57,572	207,553
Basic earnings per share	\$ 0.26	\$ 0.33	\$ 0.41	\$ 0.37	\$ 1.37
Diluted earnings per share	\$ 0.24	\$ 0.31	\$ 0.38	\$ 0.36	\$ 1.29

(1)

Restatement

During the course of the preparation of our 2003 annual consolidated financial statements, we determined that we had applied an inappropriate exchange rate to a Canadian dollar denominated long-term obligation. In December 2002, we acquired the rights, through a subsidiary whose functional currency is the U.S. dollar, to Wellbutrin® SR and Zyban® in Canada from GSK in a transaction denominated in Canadian dollars. At the date of acquisition, we recorded the acquired assets and the related long-term obligation in U.S. dollars at the exchange rate existing at that date. However, in our previously issued interim financial statements for 2003, we did not adjust the Wellbutrin® and Zyban® obligation to reflect changes in the exchange rate except for payments made on that obligation when a foreign exchange loss was recorded on the payment transactions. U.S. GAAP requires that monetary balances denominated in a currency other than an entity's functional currency be translated to reflect the exchange rates in existence at each balance sheet date. Consequently, the impact of the translation of the Wellbutrin® and Zyban® obligation, using the exchange rates existing at March 31,

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 20-F

2003, June 30, 2003 and September 30, 2003, on our previously reported interim results of operations in 2003 is summarized in the following table.

(In 000s, except per share data)	Q1	Q2	Q3
2003			
Net income as previously reported	\$ 40,760	\$ 53,166	\$ 10,222
Foreign exchange adjustments	(5,392)	(3,928)	3,129
Net income as restated	35,368	49,238	13,351
Basic earnings per share			
As previously reported	\$ 0.26	\$ 0.34	\$ 0.06
As restated	\$ 0.22	\$ 0.31	\$ 0.08
Diluted earnings per share			
As previously reported	\$ 0.26	\$ 0.33	\$ 0.06
As restated	\$ 0.22	\$ 0.31	\$ 0.08

(2)

Impact of specific events on operations

The impacts of specific events on our interim and full-year results of operations in 2003 and 2002 are identified in the following table.

(In 000s, except per share data)	Q1	Q2	Q3	Q4	Full-Year
2003					
Relocation costs	\$	\$	\$ 3,156	\$ 4,383	\$ 7,539
Write-down of assets				82,189	82,189
Extinguishment of royalty obligation				61,348	61,348
Foreign exchange loss (gain) on long-term obligation	5,392	6,601	(655)	1,723	13,061
Reduction in tax contingency provision				(12,000)	(12,000)
Total	\$ 5,392	\$ 6,601	\$ 2,501	\$ 137,643	\$ 152,137
Total per share (diluted)	\$ 0.03	\$ 0.04	\$ 0.02	\$ 0.86	\$ 0.95
2002					
Write-down of assets	\$	\$	\$ 1,369	\$ 30,575	\$ 31,944
Write-down of assets per share (diluted)	\$	\$	\$ 0.01	\$ 0.19	\$ 0.20

FINANCIAL POSITION

(In 000s)	Years ended December 31		
	2003	2002	Change
Working capital	\$ 149,884	\$ (23,527)	\$ 173,411
Long-lived assets	1,792,396	1,836,711	(44,315)
Long-term obligations	812,526	732,111	80,415
Shareholders' equity	1,266,826	1,264,787	2,039

Working capital increased by \$173.4 million to \$149.9 million at December 31, 2003 from negative \$23.5 million at December 31, 2002. The current ratio improved to 1.6:1 at December 31, 2003 from 0.9:1 at December 31, 2002. The increase in working capital was mainly due to higher cash and cash equivalents and inventory balances, and lower current portion of long-term obligations balance. The increase in inventories was mainly due to the addition of raw material and work in process inventories of Wellbutrin XL, as well as finished goods inventories of other

new products, such as Cardizem® LA, Ativan® and Isordil®. The decline in the current portion of long-term obligations reflected payments made in 2003 related to the extension of the Zovirax distribution agreement, and to the acquisition of Wellbutrin® SR and Zyban® in Canada.

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 20-F

Long-lived assets comprise property, plant and equipment, goodwill, intangible and other assets, net of accumulated depreciation and amortization. Long-lived assets declined by net \$44.3 million to \$1,792.4 million at December 31, 2003 from \$1,836.7 million at December 31, 2002. Capital expenditures on property, plant and equipment were \$36.9 million in 2003, which consisted mainly of additions to our manufacturing capacity to meet demand for the launches of Wellbutrin XL and Cardizem® LA. Additions to intangible assets in 2003 included the Ativan® and Isordil® trademarks, product rights and technology for \$125.7 million and an additional participating interest in generic omeprazole for \$35.5 million. Additions to intangible assets in 2003 also included acquired research and development, comprising: (i) \$16.0 million related to our acquisition of Tramadol FT and Tramadol/Acetaminophen FT from Ethypharm; (ii) \$26.4 million related to our interest in BNC-PHARMAPASS's carvedilol, eprosartan and tamsulosin products; (iii) \$44.2 million related to our acquisition of the Athpharma products; and (iv) \$38.1 million related to our acquisition of the Ativan® products under development. Offsetting these additions to property, plant and equipment and intangible assets was depreciation and amortization of \$256.4 million, and the write-downs of the Cedax and Rondec product rights of \$43.4 million and acquired research and development of \$37.1 million, as well as the repayment of our loan receivable from Reliant, coincident with the termination of our co-promotion arrangement with Reliant, which amounted to \$30.0 million at December 31, 2002.

Long-term obligations, including the current portion thereof, increased by \$80.4 million to \$812.5 million at December 31, 2003 from \$732.1 million at December 31, 2002. In 2003, we borrowed an additional \$170.0 million under our revolving term credit facility, for a total of \$280.0 million drawn at December 31, 2003, and we added a long-term obligation of \$17.5 million related to the acquisition of Ativan® and Isordil®. In 2003, we repaid \$119.3 million of long-term obligations related to the acquisitions of intangible assets.

Shareholders' equity increased by \$2.0 million to \$1,266.8 million at December 31, 2003 from \$1,264.8 million at December 31, 2002. The increase in shareholders' equity reflected the issuance of \$12.1 million of common shares, mainly on the exercise of stock options, and the repayment to us of \$10.0 million of Executive Stock Purchase Plan ("ESPP") loans in 2003. The increase in shareholders' equity also reflected a \$20.2 million foreign currency translation adjustment reflecting the impact of the strengthening of the Canadian dollar relative to the U.S. dollar, offset by the net loss of \$40.3 million recorded in 2003.

CASH FLOWS

At December 31, 2003, we had cash and cash equivalents of \$133.3 million compared to \$56.1 million at December 31, 2002 and \$434.9 million at December 31, 2001.

(In 000s)	Years ended December 31		
	2003	2002	2001
Cash provided by operating activities	\$ 281,979	\$ 334,104	\$ 309,082
Cash used in investing activities	(278,446)	(792,467)	(57,747)
Cash provided by financing activities	72,523	79,533	58,641
Effect of exchange rate changes on cash and cash equivalents	1,125	19	(229)
Increase (decrease) in cash and cash equivalents	\$ 77,181	\$ (378,811)	\$ 309,747

Year ended December 31, 2003

Net cash provided by operating activities was \$282.0 million in 2003, related to the following items:

A net loss of \$40.3 million.

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 20-F

Adjustments for non-cash items of \$355.6 million, which included depreciation and amortization of \$257.1 million, and a charge related to the write-down of assets of \$82.2 million.

Net changes in non-cash operating items that reduced cash flows from operations by \$33.3 million, mainly due to an increase in inventories and a decrease in income taxes payable, partially offset by a decrease in accounts receivable.

Net cash used in investing activities was \$278.4 million in 2003, related primarily to the following items:

Acquisitions of \$242.3 million of intangible assets, which included initial cash payments of \$146.3 million for Ativan® and Isordil®, \$35.5 million related to our participating interest in generic omeprazole, \$44.2 million for the Athpharma products, and \$16.0 million for Tramadol FT and Tramadol/Acetaminophen FT.

Capital expenditures of \$36.9 million.

Acquisition of our interest in BNC-PHARMAPASS for \$25.7 million, net of cash acquired.

Advance to Reliant of an additional \$40.0 million, for a total loan receivable of \$70.0 million.

Repayment in cash of \$61.1 million of the loan receivable from Reliant.

Proceeds of \$10.0 million from the Lilly settlement payment related to the disposal of the Keftab product rights.

Net cash provided by financing activities was \$72.5 million in 2003, related primarily to the following items:

Borrowings of \$170.0 million under our revolving term credit facility.

Proceeds of \$12.1 million from the issue of common shares, mainly on the exercise of stock options.

Repayment to us of \$10.0 million of ESPP loans.

Repayment of \$119.3 million of long-term obligations related to the acquisitions of intangible assets.

Overall, cash and cash equivalents increased by \$77.2 million in 2003.

Year ended December 31, 2002

Net cash provided by operating activities was \$334.1 million in 2002, related to the following items:

Net income of \$207.6 million.

Adjustments for non-cash items of \$168.5 million, which included depreciation and amortization of \$136.7 million, and a charge related to the write-down of assets of \$31.9 million, offset by a recovery of future income taxes of \$9.8 million.

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 20-F

Net changes in non-cash operating items that reduced cash flows from operations by \$41.9 million, mainly due to an increase in accounts receivable, partially offset by increases in accounts payable and accrued liabilities.

Net cash used in investing activities was \$792.5 million in 2002, related primarily to the following items:

Acquisitions of \$375.4 million of intangible assets, which included \$133.4 million for Zovirax and \$94.3 million for Teveten®, and initial cash payments of \$145.7 million for Vasotec® and Vaseretic®.

Business acquisitions, net of cash acquired, of \$240.6 million, which comprised \$178.7 million for Pharma Pass and \$61.9 million for Pharma Tech.

Acquisitions of \$85.1 million of long-term investments, which included equity investments in Ethypharm and Depomed of \$67.8 million and \$13.7 million, respectively.

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 20-F

Capital expenditures of \$61.4 million.

Advance to Reliant of \$30.0 million.

Net cash provided by financing activities was \$79.5 million in 2002, related primarily to the following items:

Net proceeds of \$384.3 million on the issue of our Notes.

Proceeds of \$112.8 million on the exercise of warrants.

Borrowings of \$110.0 million under our revolving term credit facility.

Proceeds of \$19.6 million from the issue of common shares, mainly on the exercise of stock options.

Repurchases of \$503.1 million of our common shares on the open market, under our stock repurchase program, at an average price of \$39.08 per share.

Repayment of \$42.0 million of long-term obligations related to the acquisitions of intangible assets.

Overall, cash and cash equivalents decreased by \$378.8 million in 2002.

Year ended December 31, 2001

Net cash provided by operating activities was \$309.1 million in 2001, related to the following items:

Net income of \$124.0 million.

Adjustments for non-cash items of \$163.8 million, which included depreciation and amortization of \$108.9 million, and a charge related to the write-down of assets of \$80.5 million, offset by a recovery of future income taxes of \$39.8 million.

Net changes in non-cash operating items that increased cash flows from operations by \$21.3 million, mainly due to decreases in accounts payable and accrued liabilities, partially offset by an increase in inventories.

Net cash used in investing activities was \$57.7 million in 2001, related primarily to the following items:

Capital expenditures of \$44.4 million.

Acquisitions of \$27.4 million of intangible assets, offset by the recovery of \$15 million previously paid to Elan to license its generic versions of Adalat CC.

Net cash provided by financing activities was \$58.6 million in 2001, related primarily to the following items:

Net proceeds of \$560.0 million from our November 2001 equity offering.

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 20-F

Proceeds of \$29.2 million from the issue of common shares, mainly on the exercise of stock options.

Proceeds of \$29.1 million on the exercise of warrants.

Repayments of \$210.0 million under our revolving term credit facility.

Repayments \$193.4 million of long-term obligations related to the acquisitions of intangible assets.

Repurchases of \$120.0 million of our common shares on the open market, under our stock repurchase program, at an average price of \$41.79 per share.

Interest payments of \$13.6 million on our Debentures.

Payments of \$11.3 million to redeem our Debentures.

Advance of \$10.0 million of ESPP loans.

Overall, cash and cash equivalents increased by \$309.7 million in 2001.

OFF-BALANCE SHEET ARRANGEMENTS

We did not have any off-balance sheet arrangements at December 31, 2003, other than operating leases, purchase obligations and contingent milestone payments in the normal course of business, which are reflected in the contractual obligations table below.

LIQUIDITY AND CAPITAL RESOURCES

At December 31, 2003, we had total long-term obligations of \$812.5 million, including the current portion thereof, which included the carrying value of our Notes of \$397.7 million, borrowings under our revolving term credit facility of \$280.0 million and obligations related to the acquisitions of intangible assets of \$127.8 million. At March 31, 2004, we had repaid \$80.0 million under our revolving term credit facility and \$33.1 million of obligations related to the acquisitions of intangible assets.

In March 2004, we renewed our revolving term credit facility at \$400.0 million. This facility is renewable for one-year revolving terms at the lenders' option, with a one-year term out at our option. This credit facility may be used for general corporate purposes, including acquisitions. At December 31, 2003 and March 31, 2004, we were in compliance with all financial and non-financial covenants associated with this credit facility. At December 31, 2003 and March 31, 2004, we had advances of \$280.0 million and \$200.0 million, respectively, borrowed under this credit facility, and at each of these dates we had a letter of credit with a balance of \$61.2 million issued under this credit facility. This letter of credit secures the remaining semi-annual payments we are required to make under the Vasotec® and Vaseretic® agreement. At March 31, 2004, we had a remaining balance of \$138.8 million available to borrow under this credit facility.

The following table summarizes our fixed and contingent contractual obligations at December 31, 2003.

(In 000s)	Maturities by period				
	Total	Less than 1 year	1-3 years	4-5 years	After 5 years
Long-term obligations	\$ 814,836	\$ 62,669	\$ 340,917	\$ 11,250	\$ 400,000
Operating lease obligations	38,200	6,400	12,000	6,200	13,600
Purchase obligation ⁽¹⁾	12,193	4,794	7,399		
Purchase obligation ⁽²⁾	21,167	N/A	N/A	N/A	N/A
Contingent milestone payments ⁽³⁾	134,785	N/A	N/A	N/A	N/A
Total contractual obligations	\$ 1,021,181	\$ 73,863	\$ 360,316	\$ 17,450	\$ 413,600

(1) This purchase obligation is in connection with the manufacture and supply of Vasotec® and Vaseretic®. We are obligated to make semi-annual payments to Merck for minimum product quantities (regardless of the actual product supplied).

(2) This purchase obligation is in connection with the acquisition of Ativan® and Isordil®. We will pay Wyeth a \$20.0 million additional rights payment, increasing at 10% per annum, on the approval by the FDA of the first Ativan® line extension product that may be developed by us. As this payment is contingent on receiving FDA approval of the first Ativan® line extension product, it does not have a defined maturity.

(3) This amount comprises material contingent milestone payments in connection with certain research and development collaborations with third parties. As these payments are primarily contingent on receiving regulatory approval for the products under development, they do not have defined maturities.

In November 2003, we implemented a stock repurchase program pursuant to which we are entitled to purchase up to approximately 13.2 million of our common shares on or before November 25, 2004. Any common shares purchased by us under this program will be cancelled. To April 23, 2004, we have not repurchased any common shares under this program.

We believe that our existing balance of cash and cash equivalents, together with cash expected to be generated by our operations and existing funds available under our revolving term credit facility will be sufficient to support our operational, capital expenditure and interest requirements, as well as to meet our obligations as they become due. However, in the event that we make significant future acquisitions or change our capital structure, we may be required to raise additional funds through additional borrowings or the issuance of additional debt or equity securities.

QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are exposed to financial market risks, including changes in foreign currency exchange rates, interest rates on investments and debt obligations, and equity market prices on long-term investments. We currently use derivative financial instruments to manage our exposure to interest rate risk. We use derivative financial instruments as a risk management tool and not for trading or speculative purposes.

Inflation has not had a significant impact on our results of operations.

Foreign currency risk

We operate internationally but a majority of our revenue and expense activities and capital expenditures are denominated in U.S. dollars. Our only other significant transactions are in Canadian dollars. In 2003, we incurred a foreign exchange loss of \$13.1 million related to our Canadian dollar denominated obligation to GSK for the acquisition of the rights to Wellbutrin® SR and Zyban® in Canada. We paid the final instalment related to this obligation in March 2004 and, consequently, we do not have any material remaining non-U.S. dollar denominated obligations. A 10% change in foreign currency exchange rates would not have a material effect on our consolidated results of operations, financial position or cash flows.

Interest rate risk

The primary objective of our policy for the investment of temporary cash surpluses is the protection of principal and, accordingly, we invest in high-grade money market funds, and government and corporate securities with varying maturities, but typically less than 90 days. External independent fund administrators manage our investments. As it is our intent and policy to hold these investments until maturity, we do not have a material exposure to interest rate risk.

We are exposed to interest rate risk on borrowings under our revolving term credit facility. This credit facility bears interest based on LIBOR, U.S. dollar base rate, Canadian dollar prime rate or Canadian dollar bankers' acceptance. At our option we may lock in a rate of interest for a period of up to one year.

The imputed rates of interest used to discount our long-term obligations related to the acquisitions of intangible assets are fixed and, consequently, the fair values of these obligations are affected by changes in interest rates.

The fair value of our fixed rate Notes is affected by changes in interest rates. We manage this exposure to interest rate changes through the use of interest rate swaps, which modify our exposure to interest rate fluctuations by converting one-half of our fixed rate Notes to floating rate.

Based on our overall interest rate exposure, a 10% change in interest rates would not have a material effect on our consolidated results of operations, financial position or cash flows.

Investment risk

We are exposed to investment risks on our investments in other companies. The fair values of our investments are subject to significant fluctuations due to stock market volatility and changes in general economic

conditions. We regularly review the carrying values of our investments and record losses when events and circumstances indicate that there have been other than temporary declines in their fair values.

Our initial equity investment in Ethypharm is protected in the event of any private or public financing undertaken by Ethypharm prior to June 2005. We are monitoring our investment in Ethypharm, as Ethypharm will need to achieve improvements in operating performance or a write-down of this investment may become necessary.

A 10% change in the aggregate fair values of our investments would have a material effect on our consolidated results of operations; however, it would not have a material effect on our consolidated financial position or cash flows.

RECENT ACCOUNTING PRONOUNCEMENT

In December 2001, the CICA issued Handbook Section 3870, "Stock-Based Compensation and Other Stock-Based Payments" (as amended in November 2003). CICA Handbook Section 3870 establishes standards for the recognition, measurement and disclosure of stock-based compensation, and other stock-based payments, and applies to awards granted on or after January 1, 2002. Under the provisions of Handbook Section 3870, prior to January 1, 2004, companies could either measure the compensation cost of equity instruments issued under employee compensation plans using a fair value-based method or could recognize compensation cost using another method, such as the intrinsic value-based method. However, if another method was applied, pro forma disclosure of net income or loss and earnings or loss per share was required in the financial statements as if the fair value-based method had been applied. Effective January 1, 2004, CICA Handbook Section 3870 requires that all stock-based compensation be measured and expensed using a fair value-based methodology. Prior to January 1, 2004, we recognized employee stock-based compensation under the intrinsic value-based method and provided pro forma disclosure of net income or loss and earnings or loss per share as if the fair value-based method had been applied. Effective January 1, 2004, we have adopted the fair value-based method for recognizing employee stock-based compensation on a retroactive basis to January 1, 1996, without restatement of prior periods. The cumulative effect of the change in accounting policy on prior periods resulted in a charge to deficit of \$80.8 million at January 1, 2004.

In December 2001 (as amended in June 2003), the CICA issued Accounting Guideline ("AcG") No. 13, "Hedging Relationships". AcG No.13 establishes the criteria for identification, designation, documentation and effectiveness of hedging relationships, for the purpose of applying hedge accounting. AcG No. 13 does not specify hedge-accounting methods. AcG No. 13 is to be applied to hedging relationships in effect in fiscal years beginning on or after July 1, 2003. In June 2002, the CICA's Emerging Issues Committee ("EIC") issued EIC No. 128, "Accounting for Trading, Speculative or Non-Hedging Derivative Financial Instruments". EIC No. 128 establishes that a freestanding derivative financial instrument that gives rise to a financial asset or financial liability and is entered into for trading or speculative purposes, or that does not qualify for hedge accounting under AcG No. 13 should be recognized in the balance sheet and measured at fair value, with changes in fair value recognized in net income. We have adopted the new guidelines effective January 1, 2004.

In June 2003, the CICA issued Accounting Guideline ("AcG") No. 15, "Consolidation of Variable Interest Entities". AcG No. 15 provides guidance for applying the principles in CICA Handbook Section 1590, "Subsidiaries", to certain entities. Although the CICA is contemplating amendments to this guideline, it is expected to be effective for our 2005 fiscal year. When the CICA issues the amended guideline, we will review AcG No. 15 to determine the impact, if any, on our consolidated financial statements.

Item 6. Directors, Senior Management and Employees**A. Directors and Senior Management**

The name, municipality of residence, their ages as of April 30, 2004 and position with the Company of each of the directors and executive officers are set forth below:

Name	Age	Position
Eugene N. Melnyk ⁽¹⁾ St. Philip, Barbados	44	Chairman of the Board, Chief Executive Officer and Director
Rolf K. Reininghaus ⁽¹⁾ Mississauga, Ontario, Canada	58	Senior Vice President, Corporate and Strategic Development and Director
Paul W. Haddy ⁽¹⁾⁽²⁾ Christ Church, Barbados	51	Director
Wilfred G. Bristow ⁽¹⁾⁽³⁾⁽⁴⁾ Campbellville, Ontario, Canada	72	Director
Roger Rowan ⁽¹⁾⁽²⁾ Toronto, Ontario Canada	51	Director
Sheldon Plener ⁽¹⁾⁽³⁾⁽⁴⁾ Toronto, Ontario	52	Director
Laurence Paul, MD ⁽¹⁾⁽²⁾⁽³⁾⁽⁴⁾ Los Angeles, California, USA	39	Director
Kenneth C. Cancellara, Q.C. Toronto, Ontario, Canada	57	Senior Vice President, Chief Legal Officer and Corporate Secretary
Brian H. Crombie Mississauga, Ontario, Canada	44	Senior Vice President and Chief Financial Officer
Kristine Peterson Newtown, Pennsylvania, USA	44	Senior Vice President, Commercial Operations
Gregory Szpunar, Ph.D. Chester, New Jersey, USA	46	Senior Vice President and Chief Scientific Officer

- (1) Directors serve one year terms.
- (2) Member of the Audit Committee
- (3) Member of the Compensation Committee
- (4) Member of the Nominating and Governance Committee

Mr. Melnyk has been the Chief Executive Officer since December 2001 and has been the Chairman of the Board and a Director since March 29, 1994, the effective date of the amalgamation ("the amalgamation") of the Company's predecessor entities, BCI and Trimel. Prior to that time, was the Chairman of the Board of BCI since October 1991 and was instrumental in acquiring, financing and organizing the companies or businesses that comprised BCI. Mr. Melnyk also founded Trimel and served as its President and Chief Executive Officer from 1983 through July 1991.

Mr. Reininghaus has been a Senior Vice President, and a Director since the amalgamation and has been the Senior Vice President, Corporate and Strategic Development and the President of Biovail Ventures since December 1999. Prior to that time he was President of BPC since November 1997, President, Chief Operating Officer and a Director of BCI since October 1991 and Executive Vice President and a Director of Trimel Corp. or its affiliates since November 1987. Prior to his employment by Trimel, Mr. Reininghaus was the Marketing Manager of the Canadian operations of Miles Pharmaceuticals, a division of Bayer AG.

Mr. Haddy was elected to the Board of Directors in June 2000. Mr. Haddy is the Chairman of Lake Wood Holdings Ltd. an investment and insurance advisory company. From March 1997 until December 2003, Mr. Haddy was the Chairman and Chief Executive Officer of London Life Bank and Trust Corporation, a financial institution providing international banking and segregated fund management, asset and liability

management and pooled fixed income funds. Prior thereto, Mr. Haddy was Chairman of London Life & Casualty Reinsurance Corporation since 1989.

Mr. Bristow has been a Director since the amalgamation. Prior to that time, he had been a Director of BCI since January 1993. Mr. Bristow had been a Vice President and senior investment advisor at BMO Nesbitt Burns Inc., a Canadian investment banking firm, since December 1991. From September 1975 to December 1991, he served as vice president and director of Richardson Greenshields of Canada, an investment banking firm.

Mr. Rowan was elected to the Board of Directors in June 1997. Mr. Rowan has been President and Chief Operating Officer of Watt Carmichael Inc., a private investment firm, since May 1994. Prior thereto, Mr. Rowan was the Executive Vice President and Chief Operating Officer of Watt Carmichael Inc. since 1991.

Mr. Plener was elected to the Board of Directors in June 2002. Mr. Plener is a senior partner in the Business Law practice group at the law firm of Cassels Brock and Blackwell LLP. He has been practicing with the firm since 1978. Throughout his tenure with the firm, he has been a Managing Partner, member of the firm's Executive and Operations Committee and Chairman of its Finance Committee. Mr. Plener has been lead counsel to many public and private clients in a broad range of industries including pharmaceutical companies.

Dr. Paul was elected to the Board of Directors in June 2002. Dr. Paul is a founding principal of Laurel Crown Capital, LLC, a leveraged-buyout and principal investment company based in Santa Monica, California. Prior to his work at Laurel Crown and its predecessor, Dr. Paul was a managing director at Donaldson, Lufkin, Jenrette, Inc. (DLJ), a New York based securities and brokerage firm and then Credit Suisse First Boston after its purchase of DLJ. At DLJ, Dr. Paul was responsible for building and overseeing much of the firm's life science effort. Dr. Paul received his A.B. and M.D. from Harvard University and then subsequently received his MBA from Stanford University.

Mr. Cancellara, Q.C., has been a Senior Vice President and the Chief Legal Officer since August 2002. Previously he was the Senior Vice President and General Counsel since March 1996, was appointed Secretary in April 1996, and was a director of the Company from May 1995 to June 2000. Prior to that time, Mr. Cancellara was a partner with the law firm of Cassels, Brock and Blackwell, LLP since 1980 where he held many positions including Chairman of the Executive Committee and managing partner. Mr. Cancellara holds a Juris Doctor degree from the University of Toronto Faculty of Law and a Masters of Law in Business from Osgoode Hall law school.

Mr. Crombie joined Biovail as Senior Vice President and Chief Financial Officer in May 2000. Mr. Crombie came to Biovail from The Jim Pattison Group, one of Canada's largest private holding companies where he served as Managing Director Corporate Finance from 1998 to 2000 and was responsible for corporate development and treasury. Prior to that time, he spent 7 years in finance and general management positions with The Molson Companies most recently as SVP Corporate Finance and Treasurer responsible for planning, accounting and control, corporate development, treasury and investor relations. Mr. Crombie is a graduate of The Harvard Graduate School of Business where he received his Masters in Business Administration.

Ms. Peterson joined Biovail as Senior Vice President, Commercial Operations in May 2003. Ms. Peterson came to Biovail from BMS where she spent twenty years in increasingly senior leadership roles culminating in her most recent role as Senior Vice President of Global Marketing. In that role, she was responsible for designing the organization to better integrate science and marketing earlier into the R&D process, building launch plans for several pipeline brands and evaluating external commercial opportunities. Prior to that role, she was Senior Vice President for BMS's Cardiovascular and Metabolic business in the U.S. During her career, Ms. Peterson launched several key brands, led large sales and marketing organizations, and headed BMS's generic business. She also served on the internal board for the BMS Foundation's Women Health Philanthropy since 2001. Ms. Peterson holds a Bachelor's Degree in marketing and a Masters in Business Administration from the University of Illinois.

Dr. Szpunar joined Biovail as Senior Vice President and Chief Scientific Officer in April of 2003. Dr. Szpunar came to Biovail from Pharmacia Corporation, where he was Senior Vice President for Product Development. Dr. Szpunar has held various executive and scientific positions with Pharmacia, Pharmacia and Upjohn and The Upjohn Company over the prior 19 years. These have included participation in and

responsibility for directing global R&D operations ranging from early pre-clinical development through Phase IV product support. He has served in direct leadership positions in clinical and pre-clinical pharmacokinetics and drug metabolism, biopharmaceutics research, project management, portfolio analysis, and quality assurance. Dr. Szpunar holds a Bachelors degree in Pharmacy from Wayne State University, and a Doctor of Philosophy Degree in Pharmaceutics from The University of Michigan.

B. Compensation

The following table sets forth the compensation information for each of the last three fiscal years for the Chief Executive Officer and the four other most highly compensated executive officers of the Company who served as executive officers at the end of 2003 ("**Named Executive Officers**"). This information includes the U.S. dollar value of base salaries, annual incentive compensation payments, long-term incentive compensation payments, bonuses (paid in the current year in respect of prior years' performance) and certain other compensation.

SUMMARY COMPENSATION TABLE

Name and Principal Position	Year	Annual Compensation			Long-Term Compensation			
		Salary (U.S.\$)	Bonus (U.S.\$)	Other Annual Compensation(1) (U.S.\$)	Awards			All Other Compensation(1) (U.S.\$)
					Securities Under Options Granted(2) (#)	Restricted Shares or Restricted Share Units (U.S.\$)	Payments LTIP Payouts (U.S.\$)(3)	
Eugene N. Melnyk Chairman of the Board and Chief Executive Officer	2003	668,699			300,100			
	2002	607,908			501,100		41,310,000	
	2001	552,644					78,570,000	
Brian H. Crombie(4) Senior Vice President and Chief Financial Officer	2003	393,961	219,793		135,100			
	2002	236,628	53,882		115,100			
	2001	208,819	35,495		15,000			
Kenneth C. Cancellara(4) Senior Vice President, Chief Legal Officer and Corporate Secretary	2003	401,759	219,793		135,100			
	2002	277,398	29,322		115,600			
	2001	237,122	41,654				1,499,694 1,034,331	
Rolf K. Reininghaus(4) Senior Vice President Corporate and Strategic Development	2003	386,602	219,793		135,100		7,981,136	
	2002	189,135	49,830		85,100			
	2001	143,604	91,185					
Kristine Peterson(5) Senior Vice President, Commercial Operations	2003	241,154			100,000			80,500
William S. Poole(6)(7) President, North American Pharmaceuticals	2003	412,923	60,000		15,100			
	2002	413,243	56,538		65,000			
	2001	377,353			45,000			

Notes:

- (1) Perquisites and other personal benefits for Named Executive Officers did not exceed the lesser of Cdn\$50,000 and/or 10% of the officer's annual salary and bonus for 2003. The "other" compensation paid to Ms. Peterson related to a signing bonus and to Mr. Poole related to relocation expenses.
- (2) The options are for the purchase of common shares of the Company and were granted under the Company's Stock Option Plan, as amended, established in 1993.
- (3) Relates to the value of options exercised pursuant to the Stock Option Plan, as amended, established in 1993.
- (4) Other than in respect of Mr. Melnyk, Mr. Poole and Ms. Peterson these amounts were paid in Canadian dollars and, for the purposes of this table, converted to U.S. dollars at the respective year end rates of exchange as follows: 2003 .7138; 2002 .6339 and 2001 .6278.
- (5) Ms. Peterson joined the Company on May 5, 2004.
- (6) Mr. Poole joined the Company on January 15, 2001.
- (7) Effective May 6, 2003, Mr. Poole ceased to be President, North American Pharmaceuticals.

Employment Agreements

The following is an outline of the key material terms of the employment agreements for the Named Executive Officers.

Eugene N. Melnyk, as Chairman of the Board of the Company, pursuant to a Management Agreement effective February 1, 1992, receives annual compensation for services in the amount of U.S. \$706,147, which amount is subject to 10% annual increases during the term of the Management Agreement, and is reimbursed for business related expenses. The Management Agreement also provides for the granting to Mr. Melnyk of up to 300,000 options per year. The Management Agreement will continue automatically for renewal periods of one year unless terminated by either the Company or Mr. Melnyk upon prior written notice. Mr. Melnyk is not entitled to any termination payments upon expiry or any other terminations of his employment agreement.

Kenneth C. Cancellara, as Senior Vice President, Chief Legal Officer and Corporate Secretary, pursuant to an Employment Agreement made as of March 1, 2003, receives an annual salary of U.S. \$400,000, subject to a cost of living adjustment, reimbursement of business expenses, plus the right to receive up to 50% of annual salary as a performance cash-based bonus, together with up to 100,000 options per year of which 50,000 are to be unconditionally granted and 50,000 are to be awarded, subject to the attainment of certain corporate and personal objectives. The Employment Agreement has an indefinite term. Mr. Cancellara must provide the Company with 60 days prior written notice upon his intention to terminate the contract. Where Mr. Cancellara's contract is terminated other than for cause, he is entitled to 12 months severance in lieu of notice. Where the Company enters into a transaction the result of which is that there is a change in control⁽¹⁾ of the Company, Mr. Cancellara is entitled to 24 months severance in lieu of notice and any options granted to Mr. Cancellara prior to such change of control vest immediately.

Brian H. Crombie, as Senior Vice President, Chief Financial Officer, pursuant to an Employment Agreement made as of March 1, 2003, receives an annual salary of U.S. \$400,000, subject to a cost of living adjustment, reimbursement of business expenses, plus the right to receive up to 50% of annual salary as a performance cash-based bonus, together with up to 100,000 options per year of which 50,000 are to be unconditionally granted and 50,000 are to be awarded, subject to the attainment of certain corporate and personal objectives. The Employment Agreement has an indefinite term. Mr. Crombie must provide the Company with 60 days prior written notice upon his intention to terminate the contract. Where Mr. Crombie's contract is terminated other than for cause, he is entitled to 12 months severance in lieu of notice. Where the Company enters into a transaction the result of which is that there is a change in control⁽¹⁾ of the Company, Mr. Crombie is entitled to 24 months severance in lieu of notice and any options granted to Mr. Crombie prior to such change of control vest immediately.

Rolf Reininghaus, as Senior Vice President, Corporate and Strategic Development and Director, pursuant to an Employment Agreement made as of March 1, 2003, is entitled to receive for the year 2003 an annual salary of U.S. \$400,000, subject to a cost of living adjustment, reimbursement of business expenses, plus the right to receive up to 50% of annual salary as a performance cash-based bonus, together with up to 100,000 options per year of which 50,000 are to be unconditionally granted and 50,000 are to be awarded, subject to the attainment of certain corporate and personal objectives. Mr. Reininghaus must provide the Company with 60 days prior written notice upon his intention to terminate the contract. Where Mr. Reininghaus's contract is terminated other than for cause, he is entitled to 12 months severance in lieu of notice. Where the Company enters into a transaction the result of which is that there is a change in control⁽¹⁾ of the Company, Mr. Reininghaus is entitled to 24 months severance in lieu of notice and any options granted to Mr. Reininghaus prior to such change of control vest immediately. Effective January 1, 2004, Mr. Reininghaus has been working 25 business days per quarter and his compensation and options have been correspondingly reduced.

Kristine Peterson, as Senior Vice President, Commercial Operations, pursuant to an Employment Agreement made as of March 1, 2003, receives an annual salary of U.S. \$380,000 subject to a cost of living adjustment, reimbursement of business expenses, plus the right to receive up to 50% of annual salary as a performance cash-based bonus, together with up to 100,000 options per year of which 50,000 are to be unconditionally granted and 50,000 are to be awarded, subject to the attainment of certain corporate and personal objectives. The Employment Agreement has an indefinite term. Ms. Peterson must provide the Company with 60 days prior written notice upon her intention to terminate the contract. Where Ms. Peterson's

contract is terminated other than for cause, she is entitled to 12 months severance in lieu of notice. Where the Company enters into a transaction the result of which is that there is a change in control⁽¹⁾ of the Company, Ms. Peterson is entitled to 24 months severance in lieu of notice and any options granted to Ms. Peterson prior to such change of control vest immediately.

Gregory Szpunar, as Senior Vice President, Chief Scientific Officer, pursuant to an Employment Agreement made as of March 1, 2003, receives an annual salary of U.S. \$300,000 subject to a cost of living adjustment, reimbursement of business expenses, plus the right to receive up to 50% of annual salary as a performance cash-based bonus, together with up to 100,000 options per year of which 50,000 are to be unconditionally granted and 50,000 are to be awarded, subject to the attainment of certain corporate and personal objectives. The Employment Agreement has an indefinite term. Mr. Szpunar must provide the Company with 60 days prior written notice upon his intention to terminate the contract. Where Mr. Szpunar's contract is terminated other than for cause, he is entitled to 12 months severance in lieu of notice. Where the Company enters into a transaction the result of which is that there is a change in control⁽¹⁾ of the Company, Mr. Szpunar is entitled to 24 months severance in lieu of notice and any options granted to Mr. Szpunar prior to such change of control vest immediately.

(1) Change of Control is defined as 1) the lease, exchange, license, sale or other similar disposition of all or substantially all of the assets of the Corporation in one transaction or a series of related transactions and Eugene Melnyk is no longer Chairman of the Corporation; or 2) with the approval of the stockholders of the Corporation, a merger, amalgamation, reorganization, plan of arrangement, consolidation or other similar transaction (hereinafter collectively a "Merger"), in a single transaction or a series of related transactions, the result of which Merger is that the individuals or entities acquiring voting securities of the Corporation pursuant to such Merger hold, directly or indirectly, more than 50% of the outstanding shares of the resultant Corporation and Eugene Melnyk is no longer Chairman of the Corporation; or 3) the acquisition of more than 50% of the voting securities of the Corporation by any person(s) or entity (other than Eugene Melnyk or any of his affiliates), pursuant to a tender offer or similar transaction and Eugene Melnyk is no longer Chairman of the Corporation.

Directors' and Officers' Liability Insurance

The Company maintained insurance during 2003 for the benefit of its directors and officers against certain liabilities incurred by them in their capacity as directors and officers of the Company or its subsidiaries and is subject to a limit of \$75,000,000 for the period January 1, 2003 to December 31, 2003. The policy governing such insurance is subject to standard exclusions and limitations. During the 2003 fiscal year the amount of premiums paid in respect of such insurance was \$4,004,000.

It is anticipated that the amount of premium to be paid in respect of such insurance for the 2004 fiscal year will be approximately \$6,400,000.

Remuneration and Term of Directors

The Company remunerates directors who are not officers of Biovail for services to the board, committee participation and special assignments. Remuneration for each director during 2003 (paid in U.S. dollars) was as follows:

Annual Retainer	Board of Directors	\$25,000
Annual Retainer	Board Committee Chairman Fee	
	Audit	\$10,000
	Other Committees	\$5,000
Annual Retainer	Board Committee Members	\$3,000
Meeting Attendance Fee		
	\$1,000 for attending in person and or by telephone each Board Meeting and or Committee Meeting	
	\$500 for attending a committee meeting held on the same day as a board meeting	

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 20-F

A meeting fee is paid to each non-management director for meetings that the board of directors or one or more committee of the board of directors is requested or required to attend (such as executive meetings) that are not official meetings of the board of directors. Directors are paid a fee of \$1,500 per day for special assignments at the direction of the board.

Directors are also reimbursed for travel and reasonable expenses incurred in connection with attending board meetings.

In 2003, the total remuneration and fees paid to Directors was \$258,000.

In 2003, options to purchase Common Shares were granted to directors as follows:

Name	Options Granted (#) ⁽¹⁾	Exercise Price (U.S. \$/Security)	Market Value of Securities Underlying Options on the Date of Grant (U.S. \$/Security)	Expiration Date
Wilfred Bristow	10,000	45.09	45.09	June 23, 2008
Roger Rowan	10,000	45.09	45.09	June 23, 2008
Paul Haddy	10,000	45.09	45.09	June 23, 2008
Laurence Paul	10,000	45.09	45.09	June 23, 2008
Sheldon Plener	10,000	45.09	45.09	June 23, 2008

(1) The options become exercisable as of June 23, 2004

C. Board Practices

In 2002, the Company instituted a review of its corporate governance practices. While in the past the Company had complied with all relevant regulatory regimes with respect to corporate governance, in light of certain changes to the regulatory framework, most particularly the implementation of the Sarbanes-Oxley Act in the U.S. and Bill 198 in Ontario, the Board of Directors believed that it was in the best interests of the Company and its shareholders to reassess and improve existing corporate governance policies.

The result of this review was the implementation of new policies reflecting best practices with respect to corporate governance. In addition to the existing Audit Committee, whose mandate was refined, the Company created a Charter for the Board of Directors, a Nominating and Governance Committee, a Compensation Committee and an Executive Committee (composed of a core group of senior officers of the Company). Each of these Committees are more particularly described below.

1.

Overview of the Company's Corporate Governance Best Practices

The Company has been and continues to be in compliance with all applicable U.S. and Canadian laws and regulations with respect to corporate governance (*Securities Act* (Ontario), the OBCA, the Sarbanes-Oxley Act, the rules of the TSX, the NYSE and the SEC).

The Company has created a Manual of Corporate Governance that contains detailed corporate governance provisions for the Board of Directors, the Audit Committee, the Nominating and Governance Committee, the Compensation Committee and the Executive Committee.

The majority of the Company's Board is "independent" and there are regular meetings of the external directors only, free of management and insiders, which are held by the newly appointed Independent Board Coordinator.

The Company has adopted a procedure to compel the flow and dissemination of material information "upward" to the Executive Committee to review such information from all the Company's key disciplines. These meetings, together with the management meetings and quarterly operational meetings, ensure that senior management is informed of all essential issues and strategies. A key by-product of this information flow is that the Chief Executive Officer and Chief Financial Officer certifications of public filings will be signed such that shareholders will be comfortable that the Chairman and the entire senior management team will be aware of all material information concerning the Company.

2.

Charter of the Board of Directors

The Company's Board of Directors is responsible pursuant to its Charter and at law for the general supervision of the management of the business and has a duty to act in the best interests of the Company and its shareholders. The Board of Directors carries out its Charter directly and through its committees, consisting of an Audit Committee, Compensation Committee, and Nominating and Governance Committee.

(i) Composition of the Board

The Company believes that a smaller Board is more cohesive and works more effectively than a larger Board. Moreover, the Company believes that a "substantial majority" of directors should be independent of management. The Company has investigated the independence of non-management directors and an independent law firm has provided an opinion to the Company that all non-management directors are independent.

(ii) Responsibilities

Pursuant to the Board of Directors' Charter, the Board of Directors' responsibilities include, without limitation to its general mandate, the following specific responsibilities:

- (a) Appointing an "Independent Board Coordinator" who will be responsible for specific functions to ensure the independence of the Board of Directors and to ensure access of the independent Board members to senior management. Currently, Sheldon Plener is the Independent Board Coordinator;
- (b) The assignment to the various committees of directors the general responsibility for developing the Company's approach to: (i) corporate governance issues; (ii) financial reporting and internal controls; and (iii) issues relating to compensation of officers and employees;
- (c) With the assistance of the Nominating and Corporate Governance Committee:
 - (1) The continuing evaluation of the performance of the Chief Executive Officer and management succession;
 - (2) The assessment, at least annually, of the effectiveness of the Board of Directors as a whole, the Committees of the Board of Directors and the contribution of individual Directors;
 - (3) Ensuring that an appropriate review selection process and new nominees to the Board of Directors is in place;
 - (4) Ensuring that an appropriate orientation and education program for new recruits to the Board of Directors is in place; and
 - (5) Approving securities compliance policies, including communications policies of the Company;
- (d) With the assistance of the Audit Committee:
 - (1) Ensuring the integrity of the Company's internal controls and management information systems and ensuring the Company's ethical behavior and compliance with laws and regulations, audit and accounting principles and the Company's own governing documents;

- (2) Identification of the principal risks of the Company's business and ensuring that appropriate systems are in place to manage these risks; and
- (3) Reviewing and approving of significant operational and financial matters and the provision of direction to management on these matters.

- (e) With the assistance of the Compensation Committee and the CEO, the approval of the compensation of the senior management team;
- (f) The review of a strategic planning process, approval of key strategic plans that take into account business opportunities and business risks and monitoring performance against such plans; and
- (g) The review and approval of corporate objectives and goals applicable to the Company's Senior Management.

3.

Nominating and Governance Committee

Its mandate is to assist the Board by identifying individuals qualified to become Board members and members of Board committees, to recommend to the Board the director nominees and to recommend to the Board nominees for each committee of the Board. Moreover, the Nominating and Governance Committee leads the Board in its annual review of the Board's performance and monitors the Company's corporate governance structure, develops and recommends to the Board a set of corporate governance guidelines and a Code of Business Conduct and Ethics applicable to the Company, and assists the Board in monitoring the compliance by the Company with its legal and regulatory requirements.

The Nominating and Governance Committee has three members (Sheldon Plener (Chairman), Wilfred Bristow and Laurence E. Paul).

4.

Audit Committee

The Audit Committee's central role is to provide assistance to the Board of Directors in fulfilling its financial reporting and control responsibility to the shareholders and the investment community. In this respect, the Audit Committee's primary duties and responsibilities are to:

- (a) Serve as an independent and objective party to monitor the Company's financial reporting process and internal control systems;
- (b) Review and appraise the audit activities of the Company's independent auditors and the internal auditing function; and
- (c) Provide open lines of communication among the independent auditors, financial and senior management, and the Board of Directors for financial reporting and control matters.

(i) *Composition of the Audit Committee*

The Audit Committee has three members, Laurence E. Paul (Chairman), Roger Rowan and Paul Haddy. Each member of the Audit Committee is independent of management and free from any relationship that, in the opinion of the Board of Directors, would interfere with the exercise of his independent judgment as a member of the Audit Committee. According to the Charter of the Audit Committee, all members must have a working familiarity of basic finance and accounting practices, and at least one must have accounting or related financial management expertise all of the Audit Committee members have financial management expertise.

(ii) *Other Responsibilities of the Audit Committee*

Responsibilities of the Audit Committee also include:

- (a) Making recommendations to the Board of Directors regarding the selection, independence, evaluation, fees and, if necessary, the replacement of the independent auditors;

- (b) Meeting with the auditors and management of the Company to review the scope of the proposed audit for the current year, and the audit procedures to be used;

- (c) Reviewing with management and the independent auditors, the Company's financial statements to ensure that: (1) management has reviewed the audited financial statements with the Audit Committee, including significant judgments affecting the financial statements; (2) the Audit Committee has received the assurance of both financial management and the independent auditors that the Company's financial statements are fairly presented in conformity with GAAP in all material respects; and (3) the independent auditors and senior management review the adequacy and effectiveness of the financial and accounting controls of the Company.
- (d) Making inquiries of Senior Management and the independent auditors to identify significant business, political, financial and control risks and exposures and assess the steps management has taken to minimize such risk to the Company;
- (e) Ensuring that the disclosure of the process followed by the Board of Directors and its committees, in the oversight of the Company's management of principal business risks, is complete and fairly presented; and
- (f) Reviewing and confirming of compliance with the Company's policies on internal controls, conflicts of interests, foreign corrupt practice, and other key compliance issues.

5.

Executive Committee

The Executive Committee is responsible for the provision of advice, counseling and decision-making with respect to key strategic decisions affecting and/or involving the Company and the Company's affairs. The Executive Committee provides guidance to the Board with respect to key issues affecting the Company. The Executive Committee is composed entirely of senior officers of the Company and its members are appointed by the Chairman and Chief Executive Officer of the Company. Currently, the members are Eugene Melnyk, Chairman and CEO; Kenneth Cancellara, Senior Vice President and Chief Legal Officer and Corporate Secretary; Brian Crombie, Senior Vice President, Chief Financial Officer; Kristine Peterson, Senior Vice President, Commercial Operations; Gregory Szpunar, Senior Vice President, Research & Development and Chief Scientific Officer; Rolf Reininghaus, Senior Vice President Corporate and Strategic Development; Praveen Tyle, Group Vice President, Pharmaceutical Sciences & Manufacturing; John Miszuk, Vice President, Controllor and Assistant Secretary of the Company; and Mark Durham, Vice President, Corporate Human Resources.

6.

Compensation Committee

The members of the Compensation Committee are appointed by the Board to discharge the Board's responsibilities with respect to: (a) compensation of the Company's Executive Officers (b) equity-based compensation plans, including, without limitation, stock option and restricted stock plans, in which officers or employees may participate; and (c) arrangements with Executive Officers relating to their employment relationships with the Company, including, without limitation, employment agreements, severance agreements, supplemental pension or savings arrangements, change in control agreements and restrictive covenants. The Compensation Committee generally has overall responsibility for approving and evaluating Executive Officer compensation plans, policies and programs of the Company as well as all equity-based compensation plans and policies.

(i) Composition of the Compensation Committee

The Compensation Committee has three members (Laurence E. Paul, Wilfred Bristow (Chairman) and Sheldon Plener). Each of the members of the Compensation Committee is independent. The members of the Compensation Committee are appointed by the Board on the recommendation of the Nominating and Governance Committee.

(ii) Responsibilities of the Compensation Committee

- (a) Reviews and approves corporate goals and objectives relevant to CEO compensation, evaluates the CEO's performance in light of those goals and objectives and recommend to the

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 20-F

Board the CEO's compensation level based on this evaluation. In determining the long-term incentive component of the CEO's compensation, the Compensation Committee may consider the Company's performance and relative shareholder return, the value of similar incentive awards to CEOs at comparable companies, the awards given to the CEO in past years and other factors that the Committee deems appropriate in connection with its review;

- (b) Interprets, implements, administers, reviews and approves all aspects of remuneration of the Company's Executive Officers and other key officers, including their participation in incentive-compensation plans and equity-based compensation plans;
- (c) Makes recommendations to the Board with respect to the compensation of non-employee directors, including their participating in incentive-compensation plans and equity-based compensation plans;
- (d) Develops and recommends to the Company's shareholders (to the extent shareholder approval is required by any applicable law or regulation) for their approval all stock ownership, stock option and other equity-based compensation plans of the Company, and all related policies and programs. In addition, the Compensation Committee recommends to the Board and to the Company's shareholders (to the extent shareholder approval is required by any applicable law or regulation) for their approval all equity-based compensation plans with respect to non-employee directors, and all related policies and programs; and
- (e) Monitors compliance by the Company and any recipients of stock, stock options or other equity awards under the Company's equity-based compensation plans (such as any policy that requires officers or directors to own common shares.

Pension Plan

The Company does not maintain a pension plan for its employees, officers or directors.

Stock Option Plan

The Company may grant directors and officers options to purchase common shares of the Company under the Plan (described under " Stock Option Plan" in Item 6.E below). The following tables provide information on those options granted and exercised during 2003 and held at the end of 2003 by the Named Executive Officers.

Options Granted in Last Fiscal Year

Name		Securities Under Option # ⁽¹⁾	% of Total Options Granted to Employees in Period	Exercise Price (U.S.\$/Security)	Market Value of Securities Underlying Options on the Date of Grant (U.S.\$/Security)	Expiration Date
Eugene N. Melnyk	⁽²⁾	150,000	6.5%	31.00	28.56	February 6, 2008
	⁽³⁾	100	0.0%	31.00	28.56	February 6, 2008
	⁽⁴⁾	150,000	6.5%	18.75	18.19	December 11, 2008
Brian H. Crombie	⁽²⁾	85,000	3.7%	31.00	28.56	February 6, 2008
	⁽³⁾	100	0.0%	31.00	28.56	February 6, 2008
	⁽⁴⁾	50,000	2.2%	18.75	18.19	December 11, 2008
Kenneth C. Cancellara	⁽²⁾	85,000	3.7%	31.00	28.56	February 6, 2008
	⁽³⁾	100	0.0%	31.00	28.56	February 6, 2008
	⁽⁴⁾	50,000	2.2%	18.75	18.19	December 11, 2008

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 20-F

Rolf K. Reininghaus	(2)	85,000	3.7%	31.00	28.56	February 6, 2008
	(3)	100	0.0%	31.00	28.56	February 6, 2008
	(4)	50,000	2.2%	18.75	18.19	December 11, 2008
Kristine Peterson	(5)	50,000	2.2%	39.00	38.10	May 5, 2008
	(4)	50,000	2.2%	18.75	18.19	December 11, 2008
William S. Poole	(2)	15,000	0.7%	31.00	28.56	February 6, 2008
	(3)	100	0.0%	31.00	28.56	February 6, 2008

Notes:

- (1) The options granted under the Company's Stock Option Plan, as amended, established in 1993. All options are for the purchase of common shares of the Company and are for a term of 5 years.
- (2) The options become exercisable as to a maximum of 25% on March 1st of 2003, 2004, 2005 and 2006 respectively.
- (3) The options become exercisable as of December 31, 2004.
- (4) The options become exercisable as to a maximum of 25% on March 1st of 2004, 2005, 2006 and 2007 respectively.
- (5) The options become exercisable as to a maximum of 25% on May 5th of 2003, 2004, 2005 and 2006 respectively.

AGGREGATE OPTIONS EXERCISED IN LAST FISCAL YEAR AND OPTION VALUES

Name	Securities Acquired on Exercise	Aggregate Value Realized (U.S. \$)	Unexercised Options at Fiscal Year-End Exercisable/Unexercisable ⁽²⁾ (#)	Value of Unexercised in-the-Money Options Fiscal Year-End Exercisable/Unexercisable ⁽¹⁾⁽²⁾ (U.S. \$)
Eugene N. Melnyk			1,322,600 / 625,100	1,378,800 / 411,000
Brian H. Crombie			180,100 / 205,100	/ 137,000
Kenneth C. Cancellara			230,850 / 186,350	/ 137,000
Rolf K. Reininghaus	249,400	7,981,136	84,700 / 167,600	/ 137,000
Kristine Peterson			/ 100,000	/ 137,000
William S. Poole			55,000 / 70,100	/

Notes:

- (1) Value of unexercised in-the-money options calculated using the closing price of common shares of the Company, on the NYSE on December 31, 2003 (U.S.\$21.49), less the exercise price of in-the-money options.
- (2) All share and option amounts have been adjusted to give effect to the 2 for 1 stock split completed in October 2000. The options are all for the purchase of common shares of the Company and were granted under the Company's Stock Option Plan, as amended, established in 1993.

Employee Stock Purchase Plan

The Company's EPP was approved by the shareholders at the Special Shareholders' Meeting held on January 1, 1996 and was established in 1996. The purpose of the EPP is to provide a convenient method for full-time employees of the Company to participate in the share ownership of the Company or to increase their share ownership in the Company via payroll or contractual deduction. Directors, senior officers or insiders of the Company are not eligible to participate in the EPP. The aggregate number of shares reserved for issuance under the EPP, taking into consideration stock splits, shall not exceed 1,200,000 common shares. At the discretion of a committee of the Board of Directors that administers the EPP, the Company may issue directly from treasury or purchase shares in the market from time to time to satisfy the obligations under the EPP. A participant may authorize a payroll or contractual deduction up to a maximum of 10% of the base salary or remuneration to be received during any purchase period. The purchase price shall be 90% of the fair market value per share of stock

on the date on which the eligible period ends. At December 31, 2003, a total of 64,000 shares have been issued under the EPP..

D. Employees

At December 31, 2003 we had 1,958 employees, including 130 part time positions, who were engaged within the following operations; 788 in sales and marketing, 403 in research and development, 668 in manufacturing, and 99 in general and administrative areas. At December 31, 2002 and 2001, we had 1,857 and 1,322 employees, respectively, of whom 176 and 304, respectively, were in part-time positions. None of our employees is represented by a collective bargaining agreement.

E. Share Ownership

The following table shows the number and percent of Common Shares beneficially owned by Eugene Melnyk and the officers and directors as a group (10 persons). As of April 30, 2004. Other than Mr. Melnyk, no executive officer or director of the Company beneficially owns 1% or more of the Company's Common Shares.

Name of Beneficial Owner	Common Shares Owned	Percent ⁽¹⁾
Eugene N. Melnyk ⁽²⁾	23,096,816	14.5%
Officers and directors as a group (11 persons)	24,808,998	15.6%

(1) Does not include 7,572,889 common shares issuable upon exercise of stock options outstanding under our stock option plan,

(2) Mr. Melnyk also has options to purchase 1,827,700 common shares, of which 1,390,100 are exercisable as of April 30, 2004.

Stock Option Plan

Under the Company's Stock Option Plan, as amended established in 1993 (the "Plan"), the Company may grant to directors, officers, employees, consultants and advisors options to purchase common shares. The purpose of the Plan is to provide long-term incentives and rewards to the Company's directors, officers, employees, consultants and advisors. The aggregate number of shares reserved for issuance under the Plan, taking into consideration stock splits, shall not exceed 28,000,000 common shares. The number of shares reserved for issuance to any one person under the Plan, together with shares that this person may acquire under any similar plan of the Company, may not exceed 5% of the total issued and outstanding common shares. Under the Plan, the Company designates the maximum number of shares that are subject to an option. The exercise price per share of an option is the closing market price at which the common shares are traded on the NYSE on the day prior to the date the option is granted, or if not so traded, the average between the closing bid and ask prices thereof as reported for that day.

As at April 30, 2004, the Company had granted an aggregate of 7,572,889 options, which are outstanding at exercise prices ranging from \$0.81 to \$48.07 per share. The options are exercisable on various dates up to October 6, 2010.

Item 7. Major Shareholders and Related Party Transactions

A. Major Shareholders

Biovail is not directly or indirectly owned or controlled by another corporation(s) or by any foreign government.

To the knowledge of the directors and senior officers of the Company, at April 30, 2004, the following were the only persons/entities who beneficially owned, directly or indirectly, or exercised control or direction over

common shares of the Company carrying more than ten percent of the voting rights attached to all common shares of the Company:

Name of Shareholder	Approximate Number of Common Shares Beneficially Owned, Directly or Indirectly, or over which Control or Direction is Exercised	Percentage of Outstanding Common Shares Represented
Eugene N. Melnyk	23,096,816	14.5%
Wellington Management Company	18,881,100	11.9%

The following table indicates as of April 30, 2004 the approximate total number of holders of record of Common Shares, the total number of Common Shares outstanding, the number of holders of record of Common Shares with U.S. addresses, the portion of the outstanding Common Shares held in the U.S., and the percentage of Common Shares held in the U.S.:

Total Number of Holders of Record ⁽¹⁾	Total Number of Common Shares Outstanding	Number of U.S. Holders of Record ⁽²⁾	Number of Common Shares Held by U.S. Holders of Record	Percentage of Common Shares Held by U.S. Holders of Record
1,448	159,083,640	200	141,074,335	88.7%

(1) A substantial number of the Common Shares are held by depositories, brokerage firms and financial institutions in "street name". Based upon the number of annual reports and proxy statements requested by such nominees, the Company estimates that the total number of beneficial holders of Common Shares exceeds 70,000 holders.

(2) The computation of the number of Common Shares held in the U.S. is based upon the number of holders of record with U.S. addresses. U.S. residents may beneficially own Common Shares owned of record by non-U.S. residents.

B. Related Party Transactions

In June 2001, we acquired a corporate aircraft from an entity controlled by the Chairman of the Board of Directors for cash consideration of \$10,475,000. The purchase price was based on comparable market prices for the aircraft at the time of acquisition.

Indebtedness of Executive Officers

In March 2001, the Company loaned \$600,000 to a former executive officer. This loan is secured by a charge on the former officer's personal residence. This loan does not bear interest until March 1, 2004, and thereafter bears interest at a rate equal to the Company's rate of borrowing. The loan is due on March 31, 2008.

Executive Stock Purchase Plan ("ESPP") loans

In September 2001, the Company made ESPP loans in an aggregate amount of \$9,988,000 to certain executive officers in order to finance the acquisition of common shares of the Company on the open market. These loans were full recourse and were secured by the common shares purchased pursuant to these loans and bore interest at a rate equal to the Company's rate for borrowing. Interest was payable quarterly in arrears. These loans were due and payable on September 30, 2003.

At December 31, 2003, four executive officers were indebted to the Company in an aggregate amount of \$7,990,000 in connection with the ESPP loans. To facilitate repayment of these loans, on December 31, 2003, Mr. Melnyk, Chairman of the Board and Chief Executive Officer of Biovail, in his individual capacity, made loans to these executives in an amount equal to the amount of their indebtedness to the Company and the ESPP loans from the Company were repaid. These executives pledged to Mr. Melnyk, as collateral for their loans, an aggregate of 176,080 shares of the Company and their interest in the proceeds from 200,000 options to acquire shares of the Company having a strike price of \$31.00 per share. The loan arrangements provide that there will be no recourse to these executives in addition to the collateral pledged by them, except in certain instances.

C. Interests of Experts and Counsel

Not applicable.

Item 8. Financial Information

A. Consolidated Statements and Other Financial Information

The financial statements filed as part of this annual report are filed under Item 18.

B. Litigation

From time to time, the Company becomes involved in various legal and administrative proceedings, which it considers to be in the ordinary course of business. These proceedings include product liability, intellectual property, antitrust, governmental investigations and related private litigation. There are also ordinary course employment related issues and other types of claims in which the Company routinely becomes involved but which individually and collectively are not material.

Intellectual property

RhoxalPharma Inc. ("RhoxalPharma") has filed an Abbreviated New Drug Submission ("ANDS") in Canada, seeking approval of a generic version of Tiazac®. The Company has two patents listed in the Patent Registry and has instituted legal proceedings that will prohibit the issuance of a Notice of Compliance to RhoxalPharma until said proceedings are concluded, or until the expiry of 24 months from the date of the Notice of Allegation, whichever is earlier.

Novopharm Limited ("Novopharm") has filed an ANDS in Canada, seeking approval of a generic version of Wellbutrin® SR 100 mg and 150 mg. The Company has instituted legal proceedings that will prohibit the issuance of a Notice of Compliance to Novopharm until these proceedings are concluded, or until the expiry of 24 months after the date of the Notice of Allegation, whichever is earlier.

Torpharm, Inc. ("Torpharm") has filed an Abbreviated New Drug Application ("ANDA") in the U.S., seeking approval for a generic version of Cardizem® CD (120 mg, 180 mg, 240 mg and 300 mg). The Company has instituted legal proceedings pursuant to the Hatch-Waxman Act that preclude the FDA from granting approval to Torpharm until the earliest of 30 months after the filing of the legal suit, a court decision of non-infringement or patent invalidity or a court decision to abbreviate the 30-month stay.

Torpharm has filed an ANDA in the U.S., seeking approval for a generic version of Tiazac® (120 mg, 180 mg, 240 mg, 300 mg and 360 mg). The Company has instituted legal proceedings pursuant to the Hatch-Waxman Act that preclude the FDA from granting approval to Torpharm until the earliest of 30 months after the filing of the legal suit, a final court decision of non-infringement or patent invalidity, or a court decision to abbreviate the 30-month stay.

Product liability

Biovail Pharmaceuticals, Inc. ("BPI") has been named in two Complaints alleging personal injuries arising from Plaintiffs' use of Dura-Vent, a product containing PPA and formerly marketed by BPI. The Company believes that these claims are without merit and, in the event these actions proceed further, they will be vigorously defended. These actions have been currently stayed pending the outcome of legal proceedings in a larger class of PPA actions. The Company nevertheless believes that these claims are without merit and, in the event these actions proceed further, they will be vigorously defended.

Antitrust

Several class action Complaints have been filed against the Company in which these Plaintiffs have alleged that Biovail has improperly impeded the approval of a generic form of Tiazac. The Company believes that the complaints are without merit and that the Company's actions were in accordance with its rights as contained in the Hatch-Waxman Amendments and the law. Moreover, the position of the Company is that it is not responsible for Andrx's inability to receive timely final marketing approval for its generic Tiazac considering that the Andrx product did not receive FDA approval for a lengthy period following the removal of all legal or regulatory impediments by the Company.

The Company has filed its Motion for Summary Judgment seeking to dismiss the consolidated actions.

Several consumer class action suits have been commenced jointly against the Company, Elan and Teva relating to an agreement between the Company and Elan for the in-licensing of Adalat CC products from Elan. The agreement in question has since been dissolved as a result of a settlement agreement with the Federal Trade Commission ("FTC"). Biovail believes these suits are without merit since the delay in the marketing or

out-licensing of the Company's Adalat CC product was due to manufacturing difficulties the Company encountered and not because of any improper activity on its part.

The Company has filed an extensive Motion for the summary dismissal of these actions. The Company believes that these claims are without merit and, in the event these actions proceed further, they will be vigorously defended.

The Company had received an informal enquiry from the FTC with respect to the Company's acquisition and listing of certain patents relating to its Teveten® and Teveten® HCT products. The FTC has confirmed that it is satisfied with the Company's responses and will not be pursuing further action on this matter.

Securities Class Actions

The Company has received notification that a number of Securities Class Action Complaints have been filed naming Biovail and certain officers. The Complaints allege the Defendants violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, and Rule 10b-5 promulgated thereunder. More specifically the Complaints allege that Biovail and certain of its officers and directors made materially false and misleading statements during certain specified periods of time.

The legal process will require an amended and consolidated Complaint to be filed. The Company will, thereupon, consider the appropriateness of filing a Motion for the summary dismissal of this action.

The Company believes that these claims are without merit and, in the event these actions proceed further, they will be vigorously defended.

Defamation and tort

On April 29, 2003, Jerry I. Treppel, a former analyst at Banc of America Securities, commenced an action naming as Defendants the Company and certain officers thereof, and against Michael Sitrick and Sitrick & Company, Inc. (in their capacities as consultants to the Company), in which the Plaintiff has alleged that he was defamed by the Defendants and that the Company's actions resulted in damages to him by way of lost employment and employment opportunities.

The Company has filed an extensive brief requesting the summary dismissal of this action. A decision of the Court in this regard is pending.

The Company believes that these claims are without merit and, in the event this action proceeds further, it will be vigorously defended.

Government inquiries

The Company has received notification from the U.S. Attorney, District of Massachusetts, on behalf of the U.S. Office of the Inspector General ("OIG") of Health and Human Services that a preliminary administrative inquiry has been initiated into the Company's clinical experience and marketing programs related to Cardizem® LA. The Company is providing the OIG its full cooperation in this inquiry.

The Company has received notification from the SEC indicating that the SEC is conducting an informal inquiry relating to the Company's financial performance for the fiscal year 2003. The Company is providing to the SEC its full cooperation.

The Company has received requests for information from the OSC as part of the OSC's continuous disclosure review of public companies. The Company is responding and providing all requested information to the OSC.

In addition, the Company has received notification that the OSC "is conducting a routine enquiry into the trading of Biovail Corporation" securities prior to the issuance of press releases on October 3, 2003, which provided guidance for the third quarter, and October 30, 2003, which reported the financial results for the third quarter. The Company is providing the OSC its full cooperation.

Arbitration

On March 1, 2004, Biovail Laboratories Incorporated ("BLI"), a wholly-owned subsidiary of the Company, began legal proceedings through arbitration against Teva Pharmaceuticals Curacao N.V. ("Teva Curacao").

These proceedings stem from perceived improprieties by Teva Curacao in calculating the net sales from a basket of generic products exclusively licensed to Teva Curacao, from which BLI and Teva Curacao are to calculate their respective financial entitlements. These perceived improprieties were detected through a formal audit conducted by an independent accounting firm.

The Company expects these proceedings to be completed within a year from their commencement.

The outcome of all legal proceedings the Company is involved in, including losses that may result therefrom, cannot be reasonably predicted or foreseen. Accordingly, no provisions for potential losses related to any of these proceedings have been accrued for in the accompanying consolidated financial statements.

C. Dividend Policy

We have not paid cash dividends on our Common Shares, and at this time we intend to continue this policy for the foreseeable future in order to retain earnings for the development and growth of business. Our dividend policy will be reviewed periodically depending on our financial position, capital requirements, general business conditions and on other factors.

D. Significant Changes

Except as otherwise disclosed in this annual report, there has been no material adverse change in the financial position of the Company since the date of the audited consolidated financial statements.

Item 9. The Offer and Listing Details

A. Nature of Trading Market

Our common shares are traded on the New York Stock Exchange ("NYSE") and on the Toronto Stock Exchange ("TSX") under the symbol "BVF". The last reported sales price of our common shares on April 30,

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 20-F

2004 on the NYSE was \$19.00 and on the TSX was Cdn\$26.12. The following table sets forth the high and low per share sales prices for our common shares on the NYSE and TSX for the periods indicated.

	Common Shares			
	NYSE		TSX	
	High \$	Low \$	High C\$	Low C\$
1999	23.44	8.09	33.95	11.97
2000	45.38	19.13	69.50	27.50
2001	57.18	29.03	91.00	45.80
2002				
Quarter 1	56.40	40.11	89.41	63.75
Quarter 2	52.05	26.00	81.99	39.42
Quarter 3	30.63	19.90	47.66	31.52
Quarter 4	35.22	23.52	54.91	37.40
2003				
Quarter 1	41.00	26.72	60.62	42.40
Quarter 2	51.30	35.10	69.58	49.80
Quarter 3	48.09	36.00	65.15	49.36
Quarter 4	37.77	16.51	50.69	21.50
November	24.69	18.00	32.70	23.60
December	21.99	16.51	28.35	21.50
2004				
January	26.01	21.65	33.98	28.00
February	22.88	18.03	30.30	23.90
March	21.81	15.50	29.25	20.40
April	19.49	15.56	26.74	20.45
May (through to May 12, 2004)	19.89	17.87	27.35	24.80

Market Price Volatility of Common Shares

Market prices for the securities of pharmaceutical and biotechnology companies, including our securities, have historically been highly volatile, and the market has from time to time experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies. Factors such as fluctuations in our operating results, the aftermath of public announcements by us, concern as to safety of drugs, and general market conditions, can have an adverse effect on the market price of our Common Shares and other securities.

B. Plan of Distribution

Not applicable.

C. Markets

Our Common Shares, no par value (the "**Common Shares**") are traded on the NYSE and the TSX under the symbol "BVF".

D. Selling Shareholders

Not applicable.

E. Dilution

Not applicable.

F. Expenses of the Issue

Not applicable.

Item 10. Additional Information

A. Share Capital

Not applicable.

B. Memorandum and Articles of Association

Articles of Amalgamation

We are governed by our articles of amalgamation (the "**Articles**") under the OBCA and by our by-laws (the "**By-laws**"). Our Ontario corporation number is 1402077. Our articles provide that there are no restrictions on the business we may carry on or on the powers we may exercise. Companies incorporated under the OBCA are not required to include specific objects or purposes in their articles or by-laws.

Directors

Subject to certain exceptions, including in respect of their own compensation, directors may not vote on matters in which they have a material interest. The directors are entitled to remuneration as shall from time to time be determined by the Board. The directors may exercise all of the Company's power to borrow money. These powers may be amended by resolution of the shareholders. Directors are not required to retire at a particular age. There is no requirement for the directors to hold shares.

Rights, Preferences and Dividends Attaching to Shares

Any dividend unclaimed after a period of two years from the date on which such dividend is declared to be payable shall be forfeited and shall revert to us. Each of the holders of common shares, as of the record date prior to a meeting, is entitled to attend and to cast one vote for each common share held at such annual and/or special meeting, including with respect to the re-election of directors. Subject to the provisions of our By-laws, all directors may, if still qualified to serve as directors, stand for re-election. Our board of directors is not replaced at staggered intervals.

The holders of our common shares have the right to receive dividends if and when declared. On a distribution of assets on a winding-up, dissolution or other return of capital (subject to certain exceptions) the holders of common shares shall have a right to receive their *pro rata* share of such distribution. Our shareholders have no liability to further capital calls as all shares issued and outstanding are fully paid and non-assessable. There are no sinking fund or redemption provisions in respect of common shares.

We are permitted under our Articles to issue Class A Shares on such terms and in such manner as the directors may determine. As of the date hereof, no Class A shares are issued and outstanding.

Action Necessary to Change the Rights of Shareholders

The rights attaching to the different classes of shares may be varied by special resolution passed at a meeting of that class's shareholders.

Limitations on the Rights to Own Shares

The Articles do not contain any limitations on the rights to own shares.

Annual and Special Meetings of Shareholders

We are required to mail a notice of meeting and management information circular to registered shareholders not less than 21 days prior to the date of the meeting. Such materials must be filed concurrently with the applicable securities regulatory authorities in Canada and the U.S. Subject to certain provisions of the By-laws, a quorum of two shareholders in person or represented by proxy holding or representing by proxy not

less than a prescribed percentage of the total number of issued and outstanding shares is required to properly constitute a meeting of shareholders. Shareholders and their duly appointed proxies and corporate representatives are entitled to be admitted to our annual and/or special meetings.

Other Provisions of Articles and By-laws

There are no provisions in the Articles or By-laws:

Delaying or prohibiting a change in control of the Company that operate only with respect to a merger, acquisition or corporate restructuring;

Discriminating against any existing or prospective holder of shares as a result of such shareholder owning a substantial number of shares;

Requiring disclosure of share ownership; or

Governing changes in capital, where such provisions are more stringent than those required by law.

C. Material Contracts

In the prior two years, we have not entered into any contract other than in the ordinary course of business.

D. Exchange Controls

There are currently no limitations imposed by Canadian federal or provincial laws on the rights of non-resident or foreign owners of Canadian securities to hold or vote the securities held. There are also no such limitations imposed by the Articles and Bylaws with respect to our common shares.

Investment Canada Act

Under the Investment Canada Act, the acquisition of control of a Canadian business by a "non-Canadian" will be subject to review by a government agency if it meets certain financial thresholds. A reviewable acquisition will not be allowed unless the responsible Minister finds that the investment is likely to be of "net benefit" to Canada.

An acquisition of control by a non-Canadian other than a member of the World Trade Organization ("**WTO**") will be reviewable by the Investment Review Division of Industry Canada ("**Investment Canada**"), if the value of the assets of the Canadian business of which control is being acquired is (i) Cdn\$5 million or more in the case of a "direct" acquisition of a Canadian business; (ii) Cdn\$50 million or more in the case of an "indirect" acquisition, unless the Canadian assets acquired constitute more than 50% of the asset value of all entities acquired, in which case the lower threshold of Cdn \$5 million or more applies.

These thresholds have been increased where the investor is a WTO member, including the U.S. or a WTO member-controlled company or a non-WTO investor, where the Canadian business that is subject of the acquisition is, prior to the acquisition, controlled by a WTO investor. A direct acquisition by a WTO investor or of a WTO investor-controlled business is reviewable only if it involves the direct acquisition of a Canadian business with assets of Cdn \$237 million or more for the year 2004 (this figure is adjusted annually to reflect inflation). Indirect acquisitions by WTO investors or of WTO investor-controlled businesses are not reviewable, regardless of the size of the Canadian business acquired, unless the Canadian assets acquired constitute more than 50% of the value of all entities acquired, in which case the Cdn \$237 million threshold may apply. However, Investment Canada expressed the view (in September 2002) that an indirect acquisition of control of a non-sensitive sector Canadian business does not require approval regardless of whether the value of the Canadian assets is more than 50% of the value of all of the assets that are acquired in the transaction.

These increased thresholds applicable to WTO investors do not apply to the acquisition of control of a Canadian business that is engaged in certain sensitive areas such as uranium production, financial services, transportation or culture. In the case of the acquisition of control of a cultural business, the Minister of Canadian Heritage can elect to review the transaction even where it does not exceed the lower asset threshold

tests above. Even if the transaction is not reviewable, a non-Canadian must still give notice to Investment Canada of the acquisition of control of a Canadian business within 30 days after its implementation.

Competition Act

Under the Competition Act (Canada) (the "**Competition Act**"), certain transactions are subject to pre-merger notification requirements whereby notification of the transaction and specific information in connection therewith must be provided to the Commissioner of Competition (the "**Commissioner**"). Such transactions may not be completed until (i) the applicable statutory waiting periods (namely 14 days or 42 days for a short-form or long-form filing, respectively) have expired or been earlier terminated by the Commissioner or ii) the Commissioner has issued an advance ruling certificate or has waived the obligation to notify. Where the parties elect to file a short-form notification, the Commissioner may require a long-form filing, in which case the waiting period is 42 days from the time the parties submit their long form-filing.

A proposed transaction is subject to pre-merger notification only if the parties to the transaction together with their affiliates have total assets in Canada or total revenues from sales in, from or into Canada that exceed Cdn \$400 million in aggregate value. Having met this first threshold, the parties must then provide a pre-merger notification if 1) for an acquisition of assets in Canada, the aggregate value of the assets in Canada or the gross revenues from sales in or from Canada generated by these assets exceeds Cdn \$50 million; or 2) in the case of an acquisition of shares of a company, as a result of the proposed acquisition, the person acquiring the shares, together with its affiliates, would own more than 20% (or, if the person making the acquisition already owns more than 20% or more of the voting shares of the target, then more than 50%) of the voting shares of a corporation that are publicly traded, or in the case of a company of which the shares are not publicly traded, the threshold is more than 35% of the voting shares (and more than 50% if the acquiror owns 35% or more of the voting shares of the subject company prior to making the acquisition) and the aggregate value of the assets owned by the target company or corporations controlled by that company in Canada or the revenues in or from Canada generated by those assets exceeds Cdn \$50 million.

Whether or not a pre-merger notification filing is required, the Commissioner may apply to the Competition Tribunal, a specialized tribunal empowered to deal with certain matters under the Competition Act, with respect to a "merger" (as defined in the Competition Act) and, if the Competition Tribunal finds that a merger is likely to prevent or lessen competition substantially it may order that the merger not proceed or, if the merger has been completed, order its dissolution or the disposition of some of the assets or shares involved.

E. Taxation

Canadian Federal Income Taxation

The following discussion is a summary of the principal Canadian federal income tax considerations generally applicable to a holder of our Common Shares who, at all relevant times, for the purposes of the Canadian Tax Act (as defined below), and any applicable income tax convention, is not, and is not deemed to be resident in Canada, deals at arm's length with the Company and is not affiliated with the Company, holds such Common Shares as capital property, and does not use or hold and is not deemed or otherwise considered to use or hold such Common Shares in carrying on a business in Canada (a "**Non-Resident Shareholder**"). Special rules, which are not discussed in the summary, may apply to a non-resident holder that is an insurer that carries on an insurance business in Canada and elsewhere.

This summary is based upon the current provisions of the *Income Tax Act* (Canada) (the "**Canadian Tax Act**"), the regulations thereunder, and the Company's understanding of the current administrative and assessing policies and practices of the Canada Revenue Agency published in writing prior to the date hereof. This summary takes into account all specific proposals to amend the Canadian Tax Act and the regulations thereunder publicly announced by or on behalf of the Minister of Finance (Canada) prior to the date hereof. This summary does not otherwise take into account or anticipate changes in law or administrative or assessing practice, whether by judicial, regulatory, administrative or legislative decision or action, nor does it take into account provincial, territorial or foreign tax legislation or considerations which may be different from those discussed herein.

This summary is of a general nature only and is not intended to be, nor should it be construed to be, legal or tax advice generally or to any particular holder. Holders should consult their own tax advisors with respect to their own particular circumstances.

Gains on Disposition of Common Shares

No tax will generally be payable under the Canadian Tax Act on any capital gain realized by a Non-Resident Shareholder on the disposition of such Non-Resident Shareholder's Common Shares unless the Common Shares are "taxable Canadian property" to the Non-Resident Shareholder and the Non-Resident Shareholder is not entitled to relief under an applicable income tax convention.

Generally, the Common Shares will not be taxable Canadian property to a Non-Resident Shareholder at a particular time provided that (1) the Common Shares are listed on a prescribed stock exchange (which includes the TSX) at that time, and (2) the Non-Resident Shareholder, persons with whom the Non-Resident Shareholder does not deal with at arm's length, or the Non-Resident Shareholder together with all such persons, have not owned 25% or more of the issued shares of any class or series of the capital stock of the Company at any time during the 60-month period that ends at that time. Notwithstanding the foregoing, in certain circumstances set out in the Tax Act, Common Shares could be deemed to be taxable Canadian property.

Dividends on Common Shares

Subject to the provisions of an applicable income tax convention between Canada and the country in which the Non-Resident Shareholder is resident, dividends paid or credited on the Common Shares or deemed to be paid or credited on the Common Shares to a Non-Resident Shareholder will generally be subject to non-resident withholding tax under the Canadian Tax Act at the rate of 25% of the amounts paid or credited. Under the provisions of the *Canada-U.S. Income Tax Convention*, (1980) (the "**Convention**"), the rate of withholding tax on dividends paid by the Company to a Non-Resident Shareholder that is a resident of the U.S. entitled to benefits under the Convention and is the beneficial owner of such dividends is generally reduced to (a) 5% if the Non-Resident Shareholder is a company which owns at least 10% of the Company's voting stock or (b) 15% in all other cases.

U.S. Federal Income Taxation

The following discussion is a summary of certain material U.S. federal income tax consequences of the ownership and disposition of common shares to U.S. Holders (as defined below) who hold common shares as capital assets. This discussion is based upon laws, regulations, rulings and decisions currently in effect, all of which are subject to change, retroactively or prospectively.

The discussion is for general information only and may not apply to certain categories of shareholders subject to special treatment under the Internal Revenue Code of 1986, as amended (the "**Code**"), such as Non-U.S. Holders (as defined below), holders that are passthrough entities or investors in passthrough entities, dealers or traders in securities or currencies, banks, insurance companies, traders who elect to mark-to-market their securities, persons whose "functional currency" is not the U.S. dollar, tax-exempt entities, and persons that hold common shares as a position in a straddle or as part of a "hedging," "integrated," "constructive sale" or "conversion" transaction. Moreover, the discussion summarizes only federal income tax consequences and does not address any other U.S. federal tax consequences or any state, local or other tax consequences. ACCORDINGLY, PROSPECTIVE INVESTORS ARE URGED TO CONSULT THEIR OWN TAX ADVISORS TO DETERMINE THE SPECIFIC TAX CONSEQUENCES OF THE OWNERSHIP AND DISPOSITION OF COMMON SHARES TO THEM, INCLUDING ANY U.S. FEDERAL, STATE, LOCAL OR OTHER TAX CONSEQUENCES (INCLUDING ANY TAX RETURN FILING OR OTHER TAX REPORTING REQUIREMENTS) OF THE OWNERSHIP AND DISPOSITION OF COMMON SHARES.

For purposes of the following discussion, the term "U.S. Holder" means a beneficial owner of common shares that is, for U.S. federal income tax purposes, a U.S. citizen or resident, a corporation created or organized in or under the laws of the United States or any political subdivision thereof, an estate the income of which is includable in gross income for U.S. income tax purposes regardless of its source, or a trust if (a) a U.S. court is able to exercise primary supervision over the administration of the trust and one or more United States

fiduciaries have the authority to control all substantial decisions of the trust, or (b) the trust has a valid election in effect under applicable U.S. Treasury Regulations to be treated as a United States person. A "Non-U.S. Holder" means a beneficial owner of common shares that is, for U.S. federal income tax purposes, a nonresident alien or a corporation, estate or trust that is not a U.S. Holder.

Taxation of Dividends

Subject to the following discussion of special rules applicable to "PFICs," the gross amount of any dividends, if any, paid by the Company to U.S. holders, without reduction for Canadian withholding taxes, will be taxed for U.S. federal income tax purposes at recently enacted lower rates applicable to certain qualified dividends. The maximum federal income tax rate imposed on dividends received from U.S. and certain foreign corporations for years 2003 through 2008 is 15%. Recipients of dividends from foreign corporations will be taxed at this rate, provided that certain holding period requirements are satisfied, if the dividends are received from certain "qualified foreign corporations," which generally includes corporations located in a jurisdiction with which the United States has an income tax treaty that the Secretary of the Treasury determines is satisfactory and includes an information exchange program. Dividends paid with respect to stock of a foreign corporation which is readily tradable on an established securities market in the United States will also be treated as having been received from a "qualified foreign corporation." The United States Department of the Treasury and the Internal Revenue Service have determined that the Canada-U.S. Income Tax Treaty is satisfactory for this purpose. In addition, the United States Department of the Treasury and the Internal Revenue Service have determined that common shares are considered readily tradable on an established securities market if they are listed on an established securities market in the United States such as the New York Stock Exchange. Accordingly, dividends received by U.S. Holders should be entitled to favorable treatment as dividends received with respect to stock of a "qualified foreign corporation."

In certain circumstances, U.S. Holders may be eligible to receive a foreign tax credit for the Canadian withholding taxes and, in the case of a corporate U.S. Holder owning 10% or more of the voting shares of the Company, for a portion of the Canadian taxes paid by the Company itself. Dividends paid by the Company, if any, generally will not qualify for the dividends received deduction otherwise available to corporate U.S. Holders.

The amount of any dividend paid in Canadian dollars will equal the U.S. dollar value of the Canadian dollars received calculated by reference to the exchange rate in effect on the date the dividend is distributed regardless of whether the Canadian dollars are converted into U.S. dollars. If the Canadian dollars received as a dividend are not converted into U.S. dollars on the date of receipt, a U.S. Holder will have a basis in the Canadian dollars equal to its U.S. dollar value on the date of receipt. Any gain or loss realized on a subsequent conversion or other disposition of the Canadian dollars will be treated as ordinary income or loss.

It is possible that the Company is, or at some future time will be, at least 50% owned by United States persons. Dividends paid by a foreign corporation that is at least 50% owned by United States persons may be treated as United States source income (rather than foreign source income) for foreign tax credit purposes to the extent the foreign corporation has more than an insignificant amount of United States source income. The effect of this rule may be to treat a portion of any dividends paid by the Company as United States source income. The Code permits a U.S. Holder entitled to benefits under the Canada-U.S. Income Tax Treaty to elect to treat any Company dividends as foreign source income for foreign tax credit limitation purposes if the dividend income is separated from other income items for purposes of calculating the U.S. Holder's foreign tax credit. U.S. Holders should consult their own tax advisors about the desirability of making, and the method of making, such an election.

Sale, Exchange or Other Disposition

Subject to the following discussion of special rules applicable to "PFICs," U.S. Holders will generally recognize capital gain or loss on the sale, exchange or other disposition of common shares. Such gain or loss will be long-term capital gain or loss if the common shares have been held for more than one year. Any gain or loss recognized by a U.S. Holder will generally be treated as United States source gain or loss. The deduction of capital losses is subject to limitations.

Passive Foreign Investment Company Considerations

A "passive foreign investment company" (a "**PFIC**") is any foreign corporation if, after the application of certain "look-through" rules, (i) at least 75% of its gross income is "passive income" or (ii) at least 50% of the average value of its assets is attributable to assets that produce passive income or are held for the production of passive income. The determination as to PFIC status is made annually. If a U.S. Holder is treated as owning PFIC stock, the U.S. Holder will be subject to special rules generally intended to eliminate the benefit of the deferral of U.S. federal income tax that results from investing in a foreign corporation that does not distribute all its earnings currently. These rules may adversely affect the tax treatment to a U.S. Holder of dividends paid by the Company and of sales, exchanges and other dispositions of the Company common shares, and may result in other adverse U.S. federal income tax consequences.

The Company believes that it is not currently a PFIC and does not expect to become a PFIC in the future. However, there can be no assurance that the Internal Revenue Service will not successfully challenge the Company's position or that the Company will not become a PFIC at some future time as a result of changes in its assets, income or business operations.

Information Reporting and Backup Withholding

In general, information reporting requirements will apply to dividends in respect of the common shares and the proceeds received on the disposition of common shares paid within the United States (and, in certain cases, outside the United States) to U.S. Holders other than certain exempt recipients (such as corporations), and backup withholding may apply to such amounts if the U.S. Holder fails to provide an accurate taxpayer identification number or is otherwise subject to backup withholding. The amount of any backup withholding from a payment to a U.S. Holder will be allowed as a credit against the U.S. Holder's U.S. federal income tax liability.

F. Dividends and Paying Agents

Not applicable.

G. Statements by Experts

Not applicable.

H. Documents on Display

We are subject to the informational requirements of the Securities Exchange Act of 1934, as amended, and file reports and other information with the SEC. You may read and copy any of our reports and other information at, and obtain copies upon payment of prescribed fees from, the Public Reference Room maintained by the SEC at 450 Fifth Street, N.W., Room 1024, Washington, D.C. 20549. In addition, the SEC maintains a Web site that contains reports, proxy and information statements and other information regarding registrants that file electronically with the SEC at <http://www.sec.gov>. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330.

We are required to file reports and other information with the securities commissions in all provinces of Canada. You are invited to read and copy any reports, statements or other information, other than confidential filings, that we file with the provincial securities commissions. These filings are also electronically available from the Canadian System for Electronic Document Analysis and Retrieval (SEDAR) (<http://www.sedar.com>), the Canadian equivalent of the SEC's electronic document gathering and retrieval system.

We "incorporate by reference" information that we file with the SEC, which means that we can disclose important information to you by referring you to those documents. The information incorporated by reference is an important part of this Annual Report on Form 20-F and more recent information automatically updates and supersedes more dated information contained or incorporated by reference in this Annual Report on Form 20-F.

As a foreign private issuer, we are exempt from the rules under the Securities Exchange Act of 1934, as amended, prescribing the furnishing and content of proxy statements to shareholder. We have included in this report certain information disclosed in our Proxy Statement prepared under Canadian securities rules.

We will provide without charge to each person, including any beneficial owner, to whom a copy of this Annual Report has been delivered, on the written or oral request of such person, a copy of any or all documents referred to above which have been or may be incorporated by reference in this Annual Report (not including exhibits to such incorporated information that are not specifically incorporated by reference into such information). Requests for such copies should be directed to us at the following address: Biovail Corporation, 7150 Mississauga Road, Mississauga, Ontario, Canada, L5N 8M5, Attention: Investor Relations, telephone number (905) 286-3000.

I. Subsidiary Information

At December 31, 2003, Biovail had the following principal subsidiaries:

Company	Jurisdiction of Incorporation	Nature of Business	Group Share %	Registered Office
Biovail Americas Corp.	Delaware	Holding company	100	700 Route 202/206 North Bridgewater, New Jersey
Biovail Insurance Inc.	Barbados	Captive insurance company	100	Chelston Park, Bldg 2, Collymore Rock, St. Michael, Barbados
Biovail Laboratories Incorporated	Barbados	Manufacture, development, licensing of pharmaceutical products	100	Chelston Park, Bldg 2, Collymore Rock, St. Michael, Barbados
Biovail Pharmaceuticals, Inc.	Delaware	Sales and distribution of pharmaceutical products	100	700 Route 202/206 North Bridgewater, New Jersey
Biovail SA	Switzerland	Development and licensing of pharmaceutical products	100	c/o Treuhand- und Revisionsgesellschaft Zug, Baarerstrasse 112, CH-6302 Zug, Switzerland
Biovail Technologies (Ireland) Limited	Ireland	Development of pharmaceutical products	100	3200 Lake Drive Citywest Business Campus Dublin 24
Biovail Technologies Ltd.	Delaware	Manufacture and development of pharmaceutical products	100	3701 Concorde Parkway, Chantilly, Virginia 20151
Pharma Pass SA	France	Development of pharmaceutical products	100	set 4, rue Marivaux F-75002, Paris, France

Item 11. Quantitative and Qualitative Disclosures About Market Risk

Information relating to quantitative and qualitative disclosures about market risk is detailed in Item 5.

Item 12. Description of Securities Other Than Equity Securities

A. Debt Securities

Not applicable.

B. Warrants and Rights

Not applicable.

C. Other Securities

Not applicable.

D. American Depository Shares

Not applicable.

PART II

Item 13. Defaults, Dividend Arrearages and Delinquencies

None.

Item 14. Material Modification to the Rights of Security Holders and Use of Proceeds

On December 31, 1999 we filed Articles of Amendment to effect a subdivision of our common shares on the basis of two common shares for every one common share held and an increase in our authorized capital from 120,000,000 common shares to an unlimited number of common shares. An amendment was also made to our current by-law to change the quorum requirements for shareholders meetings from two shareholders holding 51% of the outstanding shares to two shareholders holding 25% of the outstanding shares.

On October 10, 2000, we filed Articles of Amendment to effect a subdivision of our common shares on the basis of two common shares for every one common share.

Item 15. Controls and Procedures

(a)

We performed an evaluation of the effectiveness of our disclosure controls and procedures that are designed to ensure that the material financial and non-financial information required to be disclosed on Form 20-F and filed with the Securities and Exchange Commission is recorded, processed, summarized and reported timely. Based on our evaluation, our management, including the CEO and CFO, have concluded that our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended) as of the end of the period covered by this report are effective. Notwithstanding the foregoing, there can be no assurance that our disclosure controls and procedures will detect or uncover all failures of persons within Biovail to disclose material information otherwise required to be set forth in our reports.

(b)

During the course of the preparation of our 2003 annual consolidated financial statements, we identified a weakness in internal controls in that we had applied an inappropriate exchange rate to a Canadian dollar denominated long-term obligation. In December 2002, we acquired the rights, through a subsidiary whose functional currency is the U.S. dollar, to Wellbutrin® SR and Zyban® in Canada from GlaxoSmithKline plc ("GSK") in a transaction denominated in Canadian dollars. At the date of acquisition, we recorded the acquired assets and the related long-term obligation in U.S. dollars at the exchange rate existing at that date. However, in our previously issued interim financial statements for 2003, we did not adjust the Wellbutrin® and Zyban® obligation to reflect changes in the exchange rate except for payments made on that obligation when a foreign exchange loss was recorded on those transactions. U.S. GAAP requires monetary balances denominated in a currency other than an entity's functional currency be translated to reflect the exchange rates in existence at each balance sheet date.

This translation resulted in changes to previously recognized foreign exchange (gains) losses of \$5.4 million, \$3.9 million and (\$3.1) million in the first, second and third quarters, respectively. The net income (loss) per share as adjusted is \$0.36 for the first quarter, as compared with previously reported \$0.39, (\$0.03) for the second quarter, as compared with the previously reported (\$0.01) and \$0.10 for the third quarter, as compared with the previously reported \$0.08.

We have issued restated financial statements for the first three quarters of 2003 reflecting these adjustments and we have expanded our processes to better evaluate the impact of foreign exchange on our financial results. In addition we have added a new foreign exchange (gain) loss line to our financial statements for greater transparency.

Item 16. Reserved

Item 16A. Audit Committee Financial Expert

Our board of directors has determined that Dr. L. Paul is an "audit committee financial expert" and that he is independent under the applicable rules promulgated by the Securities and Exchange Commission and the New York Stock Exchange.

Item 16B. Code of Ethics

On November 8, 2002, our board of directors adopted a Code of Ethics for Senior Financial Officers that applies to our chief executive officer, chief financial officer and corporate controller.

Item 16C. Principal Accounting Fees and Services.*Fees and Services*

The table below summarizes the audit fees (expressed in thousands of US dollars) paid by the Company and its consolidated subsidiaries during each of 2002 and 2003.

	2002		2003	
	Amount	%	Amount	%
Audit Fees	\$ 709	43.9	\$ 1,301	71.7
Audit-Related Fees ⁽¹⁾	683	42.3	382	21.1
Tax Fees ⁽²⁾	220	13.6	132	7.2
All Other Fees ⁽³⁾	3	0.2		
Total	1,615	100.0%	1,815	100.0%

- (1) "Audit-related fees" are fees generally related to due diligence investigations, audits of combined financial statements prepared for purposes of the contemplated disposal of certain of our activities or of combined financial statements of companies that we acquired, review of prospectuses issued by us, and to other assignments relating to internal accounting functions and procedures.
- (2) "Tax fees" are fees for professional services rendered by our auditors for tax compliance, tax advice on actual or contemplated transactions, tax consulting associated with international transfer prices and employee tax services.
- (3) "All other fees" are principally fees related to information technology and training and support services.

Audit Committee's pre-approval policies and procedures

The audit committee of our board of directors chooses and engages our independent auditors to audit our financial statements. In 2003, our audit committee also adopted a policy requiring management to obtain the audit committee's approval before engaging our independent auditors to provide any other audit or permitted non-audit services to us or our subsidiaries. This policy, which is designed to assure that such engagements do not impair the independence of our auditors, requires the audit committee to pre-approve audit and non-audit services that may be performed by our auditors.

On a quarterly basis, we inform the audit committee of the pre-approved services actually provided by our auditors. Services of a type that are not pre-approved by the audit committee require pre-approval by the audit committee's chairman on a case-by-case basis. The chairman of our audit committee is not permitted to approve any engagement of our auditors if the services to be performed either fall into a category of services that are not permitted by applicable law or the services would be inconsistent with maintaining the auditors' independence.

D. Exemptions from the Listing Standards for Audit Committee

Not applicable.

E. Purchases of Equity Securities by the Issuer and Affiliated Purchases

Not applicable.

PART III

Item 17. Financial Statements

The Company has elected to provide financial statements pursuant to Item 18.

Item 18. Financial Statements

123

INDEX TO FINANCIAL STATEMENTS

	Page
BIOVAIL CORPORATION Financial Statements completed in accordance with U.S. GAAP	
Management Report	F-2
Auditors' Report	F-3
Consolidated Balance Sheets as at December 31, 2003 and 2002	F-4
Consolidated Statements of Income (Loss) for the years ended December 31, 2003, 2002 and 2001	F-5
Consolidated Statements of Shareholders' Equity for the years ended December 31, 2003, 2002 and 2001	F-6
Consolidated Statements of Cash Flows for the years ended December 31, 2003, 2002 and 2001	F-8
Notes to the Consolidated Financial Statements	F-9
BIOVAIL CORPORATION Financial Statements completed in accordance with Canadian GAAP	
Management Report	F-46
Auditors' Report	F-47
Consolidated Balance Sheets as at December 31, 2003 and 2002	F-48
Consolidated Statements of Income for the years ended December 31, 2003, 2002 and 2001	F-49
Consolidated Statements of Shareholders' Equity for the years ended December 31, 2003, 2002 and 2001	F-50
Consolidated Statements of Cash Flows for the years ended December 31, 2003, 2002 and 2001	F-52
Notes to the Consolidated Financial Statements	F-53
	F-1

BIOVAIL CORPORATION

MANAGEMENT REPORT

The Company's management is responsible for preparing the accompanying consolidated financial statements in conformity with United States generally accepted accounting principles ("GAAP"). In preparing these consolidated financial statements, management selects appropriate accounting policies and uses its judgment and best estimates to report events and transactions as they occur. Management has determined such amounts on a reasonable basis in order to ensure that the consolidated financial statements are presented fairly, in all material respects.

The consolidated financial statements and information contained in the Management's Discussion and Analysis ("MD&A") necessarily include amounts based on informed judgments and estimates of the expected effects of current events and transactions with appropriate considerations to materiality. In addition, in preparing the financial information management must interpret the requirements described above, make determinations as to the relevancy of information to be included, and make estimates and assumptions that affect reported information. The MD&A also includes information regarding the estimated impact of current transactions and events, sources of liquidity and capital resources, operating trends, risks and uncertainties. Actual results in the future may differ materially from our present assessment of this information because future events and circumstances may not occur as expected.

The Company maintains a system of internal accounting controls designed to provide reasonable assurance, at a reasonable cost, that assets are safeguarded and that transactions are executed and recorded in accordance with the Company's policies for doing business. This system is supported by written policies and procedures for key business activities; the hiring of qualified, competent staff; and by a continuous planning and monitoring program.

Ernst & Young LLP has been engaged by the Company's shareholders to audit the consolidated financial statements. During the course of their audit, Ernst & Young LLP reviewed the Company's system of internal controls to the extent necessary to render their opinion on the consolidated financial statements.

The Board of Directors is responsible for ensuring that management fulfills its responsibility for financial reporting and is ultimately responsible for reviewing and approving the financial statements. The Board carries out the responsibility principally through its Audit Committee. The members of the Audit Committee are outside Directors. The Committee considers, for review by the Board of Directors and approval by the shareholders, the engagement or reappointment of the external auditors. Ernst & Young LLP has full and free access to the Audit Committee.

Management acknowledges its responsibility to provide financial information that is representative of the Company's operations, is consistent and reliable, and is relevant for the informed evaluation of the Company's activities.

/s/ EUGENE N. MELNYK

/s/ BRIAN H. CROMBIE

EUGENE N. MELNYK
Chairman of the Board and
Chief Executive Officer

BRIAN H. CROMBIE
Senior Vice President and
Chief Financial Officer

F-2

BIOVAIL CORPORATION

AUDITORS' REPORT

To the Shareholders of
Biovail Corporation

We have audited the consolidated balance sheets of **Biovail Corporation** at December 31, 2003 and 2002 and the consolidated statements of income (loss), shareholders' equity and cash flows for each of the years in the three-year period ended December 31, 2003. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with Canadian and United States generally accepted auditing standards. Those standards require that we plan and perform an audit to obtain reasonable assurance whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation.

In our opinion, these consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2003 and 2002 and the results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2003 in accordance with United States generally accepted accounting principles.

As discussed in note 2 to the consolidated financial statements, during 2002 the Company changed its method of accounting for goodwill and intangible assets.

On April 23, 2004, we reported separately to the shareholders of **Biovail Corporation** on the consolidated financial statements for the same periods, prepared in accordance with Canadian generally accepted accounting principles.

Toronto, Canada,
April 23, 2004

/s/ ERNST & YOUNG LLP
ERNST & YOUNG LLP
Chartered Accountants

BIOVAIL CORPORATION

CONSOLIDATED BALANCE SHEETS

In accordance with U.S. generally accepted accounting principles
(All dollar amounts expressed in thousands of U.S. dollars)

	At December 31	
	2003	2002
ASSETS		
Current		
Cash and cash equivalents	\$ 133,261	\$ 56,080
Accounts receivable	179,374	190,980
Inventories	84,058	53,047
Deposits and prepaid expenses	15,759	21,524
	<u>412,452</u>	<u>321,631</u>
Long-term investments	113,546	79,324
Property, plant and equipment, net	173,804	136,784
Goodwill, net	100,814	102,212
Intangible assets, net	1,049,475	1,080,503
Other assets, net	72,683	113,350
	<u>\$ 1,922,774</u>	<u>\$ 1,833,804</u>
LIABILITIES		
Current		
Accounts payable	\$ 67,932	\$ 71,641
Accrued liabilities	105,201	106,005
Minority interest	679	
Income taxes payable	24,175	35,691
Deferred revenue	5,765	9,231
Current portion of long-term obligations	58,816	122,590
	<u>262,568</u>	<u>345,158</u>
Deferred revenue	14,500	18,200
Long-term obligations	764,111	624,760
	<u>1,041,179</u>	<u>988,118</u>
SHAREHOLDERS' EQUITY		
Common shares, no par value, unlimited shares authorized, 158,796,978 and 158,120,144 issued and outstanding at December 31, 2003 and 2002, respectively	1,448,353	1,433,624
Stock options outstanding	2,290	4,856
Executive Stock Purchase Plan loans		(9,988)
Deficit	(607,678)	(580,413)
Accumulated other comprehensive income (loss)	38,630	(2,393)
	<u>881,595</u>	<u>845,686</u>
	<u>\$ 1,922,774</u>	<u>\$ 1,833,804</u>

At December 31

Commitments and contingencies (notes 3, 23 and 24)

On behalf of the Board:

/s/ EUGENE N. MELNYK
EUGENE N. MELNYK
Chairman of the Board and
Chief Executive Officer

/s/ LAURENCE E. PAUL
LAURENCE E. PAUL, M.D.
Director

The accompanying notes are an integral part of the consolidated financial statements.

F-4

BIOVAIL CORPORATION

CONSOLIDATED STATEMENTS OF INCOME (LOSS)

In accordance with U.S. generally accepted accounting principles
(All dollar amounts expressed in thousands of U.S. dollars, except per share data)

	Years ended December 31		
	2003	2002	2001
REVENUE			
Product sales	\$ 632,898	\$ 645,986	\$ 521,154
Research and development	14,239	28,425	14,596
Co-promotion, royalty and licensing	176,585	113,614	47,513
	<u>823,722</u>	<u>788,025</u>	<u>583,263</u>
EXPENSES			
Cost of goods sold	139,456	164,706	125,995
Research and development	86,570	52,150	51,017
Selling, general and administrative	242,771	166,397	109,028
Amortization	140,895	71,499	44,513
Write-down of assets	45,081	31,944	80,482
Acquired research and development	124,720	167,745	
Extinguishment of royalty obligation	61,348		
Settlements	(34,055)		
	<u>806,786</u>	<u>654,441</u>	<u>411,035</u>
Operating income	16,936	133,584	172,228
Interest income	7,165	3,608	2,742
Interest expense	(40,421)	(32,005)	(36,242)
Foreign exchange gain (loss)	(14,007)	700	(1,072)
Other income (expense)	(938)	3,408	
Debt conversion premiums			(34,923)
	<u>(31,265)</u>	<u>109,295</u>	<u>102,733</u>
Income (loss) before provision for (recovery of) income taxes	(31,265)	109,295	102,733
Provision for (recovery of) income taxes	(4,000)	21,500	15,285
	<u>(27,265)</u>	<u>87,795</u>	<u>87,448</u>
Net income (loss)	\$ (27,265)	\$ 87,795	\$ 87,448
Earnings (loss) per share			
Basic	\$ (0.17)	\$ 0.58	\$ 0.64
Diluted	\$ (0.17)	\$ 0.55	\$ 0.58
Weighted average number of common shares outstanding (000s)			
Basic	158,516	151,960	136,928
Diluted	158,516	160,463	150,690

The accompanying notes are an integral part of the consolidated financial statements.

BIOVAIL CORPORATION

CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY

In accordance with U.S. generally accepted accounting principles
(All dollar amounts expressed in thousands of U.S. dollars)

Common shares

	Shares (000s)	Amount	Stock options outstanding	Executive Stock Purchase Plan loans	Warrants outstanding	Deficit	Accumulated other comprehensive income (loss)	Total
Balance, January 1, 2001	131,461	\$ 482,842	\$ 9,891	\$	\$ 7,912	\$ (261,819)	\$ (1,368)	\$ 237,458
Issued on the exercise of stock options	2,906	33,650	(4,826)					28,824
Issued under Employee Stock Purchase Plan	6	280						280
Cancelled under stock repurchase program	(2,871)	(14,354)				(105,633)		(119,987)
Issued pursuant to equity offering	12,500	587,500						587,500
Issue costs		(27,454)						(27,454)
Issued on surrender and redemption of Convertible Subordinated Preferred Equivalent Debentures	10,433	314,259						314,259
Issued on exercise of warrants	3,061	30,784			(1,691)			29,093
Cancellation of non-employee options			(735)					(735)
Compensation cost for employee stock options			737					737
Advance of Executive Stock Purchase Plan loans				(9,988)				(9,988)
	157,496	1,407,507	5,067	(9,988)	6,221	(367,452)	(1,368)	1,039,987
Net income						87,448		87,448
Other comprehensive loss								
Foreign currency translation adjustment							(2,254)	(2,254)
Unrealized holding losses on long-term investments							(72)	(72)
Reclassification adjustment for loss on long-term investment included in net income							965	965
Other comprehensive loss							(1,361)	(1,361)
Comprehensive income								86,087
Balance, December 31, 2001	157,496	1,407,507	5,067	(9,988)	6,221	(280,004)	(2,729)	1,126,074
Issued on the exercise of stock options	2,197	21,506	(2,210)					19,296
Issued under Employee Stock Purchase Plan	17	463						463
Cancelled under stock repurchase program	(12,872)	(114,896)				(388,204)		(503,100)
Issued on exercise of warrants	11,282	119,044			(6,221)			112,823
Compensation cost for employee stock options			1,999					1,999

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 20-F

Common shares

	158,120	1,433,624	4,856	(9,988)	(668,208)	(2,729)	757,555
Net income					87,795		87,795
Other comprehensive income							
Foreign currency translation adjustment						336	336
Other comprehensive income						336	336
Comprehensive income							88,131
Balance, December 31, 2002	158,120	1,433,624	4,856	(9,988)	(580,413)	(2,393)	845,686

F-6

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 20-F

Common shares

	Shares (000s)	Amount	Stock options outstanding	Executive Stock Purchase Plan loans	Warrants outstanding	Deficit	Accumulated other comprehensive income (loss)	Total
Issued on the exercise of stock options	663	14,247	(2,650)					11,597
Issued under Employee Stock Purchase Plan	14	482						482
Compensation cost for employee stock options			84					84
Repayment of Executive Stock Purchase Plan loans				9,988				9,988
	158,797	1,448,353	2,290			(580,413)	(2,393)	867,837
Net loss						(27,265)		(27,265)
Other comprehensive income								
Foreign currency translation adjustment							20,233	20,233
Unrealized holding gains on long-term investments							20,790	20,790
Other comprehensive income							41,023	41,023
Comprehensive income								13,758
Balance, December 31, 2003	158,797	\$ 1,448,353	\$ 2,290	\$	\$	\$ (607,678)	\$ 38,630	\$ 881,595

The accompanying notes are an integral part of the consolidated financial statements.

BIOVAIL CORPORATION

CONSOLIDATED STATEMENTS OF CASH FLOWS

In accordance with U.S. generally accepted accounting principles
(All dollar amounts expressed in thousands of U.S. dollars)

	Years ended December 31		
	2003	2002	2001
CASH FLOWS FROM OPERATING ACTIVITIES			
Net income (loss)	\$ (27,265)	\$ 87,795	\$ 87,448
Add (deduct) items not involving cash			
Depreciation and amortization	157,317	82,368	55,287
Amortization of deferred financing costs	2,975	2,267	1,580
Amortization of discounts on long-term obligations	6,562	5,329	10,999
Compensation cost for employee stock options	84	1,999	737
Write-down of assets	45,081	31,944	80,482
Acquired research and development	124,720	167,745	
Debt conversion premiums, net of cash paid			23,574
Interest paid through the issuance of common shares			1,250
Other	5,809	(3,408)	1,450
	<u>315,283</u>	<u>376,039</u>	<u>262,807</u>
Net change in non-cash operating items	(33,304)	(41,935)	21,314
	<u>281,979</u>	<u>334,104</u>	<u>284,121</u>
CASH FLOWS FROM INVESTING ACTIVITIES			
Acquisitions of intangible assets	(242,298)	(375,385)	(27,445)
Additions to property, plant and equipment	(36,923)	(61,382)	(44,436)
Acquisitions of businesses, net of cash acquired	(25,741)	(240,581)	
Acquisitions of long-term investments	(4,555)	(85,119)	(866)
Advance of loan receivable	(40,000)	(30,000)	
Repayment of loan receivable	61,071		
Proceeds on disposal of intangible asset	10,000		
Proceeds on reduction in intangible assets			15,000
	<u>(278,446)</u>	<u>(792,467)</u>	<u>(57,747)</u>
CASH FLOWS FROM FINANCING ACTIVITIES			
Issuance of common shares, net of issue costs	12,079	19,615	589,150
Repayment (advance) of Executive Stock Purchase Plan loans	9,988		(9,988)
Repurchase of common shares		(503,100)	(119,987)
Proceeds from exercise of warrants		112,823	29,093
Advances (repayments) under revolving term credit facility, including financing costs	169,800	107,895	(211,300)
Repayments of other long-term obligations	(119,344)	(41,980)	(193,366)
Issuance of Senior Subordinated Notes, net of financing costs		384,280	
	<u>72,523</u>	<u>79,533</u>	<u>83,602</u>

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 20-F

	Years ended December 31		
	2019	2018	2017
Effect of exchange rate changes on cash and cash equivalents	1,125	19	(229)
Net increase (decrease) in cash and cash equivalents	77,181	(378,811)	309,747
Cash and cash equivalents, beginning of year	56,080	434,891	125,144
Cash and cash equivalents, end of year	\$ 133,261	\$ 56,080	\$ 434,891

The accompanying notes are an integral part of the consolidated financial statements.

BIOVAIL CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

**In accordance with U.S. generally accepted accounting principles
(All tabular dollar amounts expressed in thousands of U.S. dollars, except per share data)**

1. GOVERNING STATUTE AND NATURE OF OPERATIONS

Biovail Corporation ("Biovail" or the "Company") is incorporated under the laws of the Province of Ontario, Canada. The Company is a full-service pharmaceutical company, engaged in the formulation, clinical testing, registration, manufacture, promotion and sale of pharmaceutical products utilizing advanced oral drug delivery technologies. The Company's main therapeutic areas of focus are cardiovascular (including Type II diabetes), central nervous system and pain management. The Company's common shares trade on the New York Stock Exchange ("NYSE") and the Toronto Stock Exchange ("TSX") under the symbol BVF.

2. SIGNIFICANT ACCOUNTING POLICIES

Basis of presentation

The consolidated financial statements have been prepared by the Company in U.S. dollars and in accordance with U.S. generally accepted accounting principles ("GAAP"), applied on a consistent basis (except as described below under goodwill and intangible assets). Consolidated financial statements prepared in U.S. dollars and in accordance with Canadian GAAP will be separately made available to all shareholders and filed with necessary regulatory authorities.

Principles of consolidation

The consolidated financial statements include the accounts of the Company and those of all its wholly-owned and majority-owned subsidiaries. All significant intercompany transactions and balances have been eliminated.

Use of estimates

In preparing the Company's consolidated financial statements, management is required to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenue and expenses during the reporting periods. Under certain agreements, management relies on estimates and assumptions made by the Company's third party licensees. On an ongoing basis, management reviews its estimates to ensure that these estimates appropriately reflect changes in the Company's business and new information as it becomes available. Significant estimates made by management include allowances for accounts receivable and inventories, provisions for product returns, recalls, rebates and chargebacks, the useful lives of long-lived assets, the expected future cash flows used in evaluating long-lived assets and investments for impairment, the realizability of deferred tax assets, and the allocation of the purchase price of acquired assets and businesses. If historical experience and other factors used by management to make these estimates do not reasonably reflect future activity, the Company's financial position and results of operations could be materially impacted.

Fair value of financial instruments

Fair value of a financial instrument is defined as the amount at which the instrument could be exchanged in a current transaction between willing parties. The estimated fair values of cash equivalents, accounts receivable, accounts payable, accrued liabilities and income taxes payable approximate their carrying values due to their short maturity periods. The fair values of long-term investments and long-term obligations are based on quoted market prices, if available, or estimated discounted future cash flows. The fair values of derivative contracts are estimated based on the amount that would have been received or paid to settle these contracts.

Cash and cash equivalents

Cash and cash equivalents include highly liquid investments with original maturities of 90 days or less when purchased.

Accounts receivable

The Company performs ongoing credit evaluations of customers and generally does not require collateral. Allowances are maintained for potential credit losses.

Inventories

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 20-F

Inventories comprise raw materials, work in process and finished goods, which are valued at the lower of cost or market, on a first-in, first-out basis. Cost for work in process and finished goods inventories includes materials, direct labour and an allocation of overheads. Market for raw materials is replacement cost, and for work in process and finished goods is net realizable value.

F-9

Long-term investments

Long-term investments with readily determinable market values, where the Company does not have the ability to exercise significant influence, are accounted for as being available-for-sale. These investments are reported at fair value with all unrealized gains and temporary unrealized losses recognized in comprehensive income or loss. Unrealized losses on these investments that are considered to be other than temporary are recognized in net income or loss.

Long-term investments without readily determinable market values, where the Company does not have the ability to exercise significant influence, are accounted for using the cost method. Declines in the fair value of these investments below their cost basis that are considered to be other than temporary are recognized in net income or loss.

A long-term investment, where the Company has the ability to exercise significant influence, is accounted for using the equity method. The Company's share of the earnings or losses of this company is recognized in net income or loss.

Property, plant and equipment

Property, plant and equipment are reported at cost, less accumulated depreciation. Cost includes interest costs attributable to major capital projects prior to the related assets becoming available for productive use. Depreciation is calculated using the straight-line method, commencing when the assets become available for productive use, based on the following estimated useful lives:

Buildings	25 years
Machinery and equipment	5-10 years
Other equipment	3-10 years
Leasehold improvements	Term of lease

The Company evaluates property, plant and equipment for impairment whenever events or changes in circumstances indicate that the carrying amounts of these assets may not be recoverable. This evaluation is performed by comparing the carrying amounts of these assets to the related estimated undiscounted future cash flows. If these cash flows are less than the carrying amount of the asset, then the carrying amount of the asset is written down to its fair value.

Goodwill and intangible assets

Goodwill represents the excess of the purchase price of acquired businesses over the fair value of the identifiable net assets acquired. Intangible assets acquired through asset acquisitions or business combinations are initially recognized at fair value based on an allocation of the purchase price.

Effective January 1, 2002, the Company adopted the Financial Accounting Standards Board ("FASB") Statement of Financial Accounting Standards ("SFAS") No. 142, "Goodwill and Other Intangible Assets". Under SFAS No. 142, goodwill and other intangible assets deemed to have indefinite lives are no longer amortized, but are subject to annual impairment tests. Intangible assets with finite lives continue to be amortized over their estimated useful lives.

Effective January 1, 2002, the Company identified those intangible assets that did not meet the criteria for recognition apart from goodwill, and assessed the useful lives of its remaining intangible assets. As a result, the Company reclassified the \$5,722,000 net carrying amount of workforce related intangible assets to goodwill and determined that the useful lives of its remaining intangible assets were appropriate and consistent with those useful lives identified at December 31, 2001. The Company does not have any indefinite-lived intangible assets.

On an annual basis, the Company evaluates its goodwill for impairment by comparing the fair values of its reporting units to their respective carrying values. In 2003, the Company completed the annual evaluation of its goodwill and recorded a write-down of \$1,681,000 related to the impairment of goodwill associated with its Swiss subsidiary, Biovail S.A., due to a decline in royalties earned on the sales of products out-licensed by this subsidiary.

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 20-F

A reconciliation of reported net income or loss and earnings or loss per share, assuming SFAS No. 142 was applied retroactively, is as follows:

	2003	2002	2001
Net income (loss) as reported	\$ (27,265)	\$ 87,795	\$ 87,448
Goodwill amortization			5,583
Workforce amortization			1,071
	\$ (27,265)	\$ 87,795	\$ 94,102
Basic earnings (loss) per share			
Net income (loss) as reported	\$ (0.17)	\$ 0.58	\$ 0.64
Goodwill amortization	\$	\$	\$ 0.04
Workforce amortization	\$	\$	\$ 0.01
	\$ (0.17)	\$ 0.58	\$ 0.69
Diluted earnings (loss) per share			
Net income (loss) as reported	\$ (0.17)	\$ 0.55	\$ 0.58
Goodwill amortization	\$	\$	\$ 0.04
Workforce amortization	\$	\$	\$ 0.01
	\$ (0.17)	\$ 0.55	\$ 0.63

Intangible assets are reported at cost, less accumulated amortization. Amortization is generally calculated using the straight-line method based on the following estimated useful lives:

Trademarks	20 years
Product rights	8-20 years
Technology	15 years

The Company obtained a participating interest in the gross profit on sales of generic omeprazole (as described in note 3 Acquisitions). This interest is being amortized on a proportionate basis relative to the revenue received from this interest.

The Company evaluates intangible assets for impairment whenever events or changes in circumstances indicate that the carrying amounts of these assets may not be recoverable. This evaluation is performed by comparing the carrying amounts of these assets to the related estimated undiscounted future cash flows. If these cash flows are less than the carrying amount of the asset, then the carrying amount of the asset is written down to its fair value.

Deferred financing costs

Deferred financing costs are reported at cost, less accumulated amortization. Amortization is calculated using the straight-line method over the term of the following related obligations:

Revolving term credit facility	3 years
Senior Subordinated Notes	8 years

Amortization expense related to deferred financing costs is included in interest expense.

Deferred compensation plan

The Company maintains a deferred compensation plan to provide certain employees with the opportunity to supplement their retirement income through the deferral of pre-tax income. The assets of this plan were placed in trust, and have been recorded in other assets with a corresponding liability recorded in long-term obligations. The terms of the trust agreement state that the assets of the trust are available to satisfy the claims of general creditors of the Company in the event of bankruptcy, thereby qualifying this trust as a rabbi

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 20-F

trust for income tax purposes. Changes in the value of the assets held by this trust, and a corresponding charge or credit to compensation expense (to reflect the fair value of the amount owed to the participants), are recognized in net income or loss.

Derivative financial instruments

The Company manages its exposure to interest rate risks through the use of derivative financial instruments that are designated as a fair value hedge of an identified portion of a recognized long-term obligation. The Company does not utilize derivative financial instruments for trading or speculative purposes. The Company accounts for derivative financial instruments as either assets or liabilities at fair value. For a derivative financial instrument that is designated and qualifies as a highly effective fair value hedge, the derivative financial instrument is marked-to-market with the gain or loss on the derivative financial instrument and the respective offsetting loss or gain on the underlying hedged item recognized in net income or loss. Net receipts or payments relating to the derivative financial instruments are recorded as an adjustment to interest expense.

Foreign currency translation

The financial statements of the Company's operations having a functional currency other than U.S. dollars are translated into U.S. dollars at the rate of exchange prevailing at the balance sheet date for asset and liability accounts and at the average rate of exchange for the reporting period for revenue and expense accounts. The cumulative foreign currency translation adjustment is recorded as a component of accumulated other comprehensive income or loss in shareholders' equity. Foreign currency gains and losses related to the remeasurement of the Company's Irish operations are recognized in net income or loss.

Foreign currency exchange gains and losses on transactions occurring in a currency other than an operation's functional currency are recognized in net income or loss.

Revenue recognition

Revenue is deemed to be realizable and earned when persuasive evidence of an arrangement exists, delivery has occurred or services have been rendered, the seller's price to the buyer is fixed or determinable, and collectibility is reasonably assured.

Effective January 1, 2000, the Company implemented the provisions of the U.S. Securities and Exchange Commission's ("SEC") Staff Accounting Bulletin ("SAB") No. 101, "Revenue Recognition in Financial Statements". Total revenue in 2003, 2002 and 2001 included \$5,200,000, \$4,800,000 and \$6,300,000, respectively, of amortization of revenue deferred on the implementation of SAB No. 101.

Product sales

Product sales revenue is recognized when title has transferred to the customer, provided that the Company has not retained any significant risks of ownership or future obligations with respect to the product sold. Amounts received from customers as prepayments for products to be shipped in the future are reported as deferred revenue.

Revenue from product sales is recognized net of provisions for estimated sales discounts and allowances, returns, recalls, rebates and chargebacks. In connection with these provisions related to sales of products manufactured by the Company for distribution by third party licensees, the Company relies on estimates and assumptions made by these licensees. Provisions for sales discounts and allowances are estimated based on contractual sales terms with customers and historical payment experience. Provisions for returns and recalls are estimated based on historical return and exchange levels, and third party data with respect to inventory levels in the Company's distribution channels. Provisions for rebates and chargebacks are estimated based on historical experience, contractual sales terms with wholesalers and indirect customers, and relevant statutes with respect to governmental pricing programs.

Research and development

Research and development revenue attributable to the performance of contract services is recognized as the services are performed, in accordance with the terms of the specific development contracts. On long-term research and development collaborations, revenue is recognized on a proportionate basis relative to the total level of effort necessary to meet all regulatory and developmental requirements. Costs and profit margin related to these collaborations that are in excess of amounts billed are recorded in accounts receivable, and amounts billed related to these collaborations that are in excess of costs and profit margin are recorded in deferred revenue. Contingent revenue attributable to the achievement of regulatory or developmental milestones is recognized only on the achievement of the applicable milestone. Non-refundable, up-front fees for access to the Company's proprietary technology in connection with certain

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 20-F

research and development collaborations are deferred and recognized as revenue on a systematic basis over the term of the related collaboration.

Co-promotion

Co-promotion revenue is recognized based on the terms of the specific co-promotion contracts, and is generally determined based on a percentage of the net sales of the co-promoted products. Sales and marketing costs related to co-promotion revenue are recorded in selling, general and administrative expenses.

Royalty and licensing

Royalty revenue is recognized based on the terms of the specific licensing contracts, and when the Company has no future obligations pursuant to the royalty fee. Royalty revenue is recognized net of amounts payable to sublicensees where the Company is simply acting as an agent for the sublicensee. Licensing revenue is deferred and recognized on a systematic basis over the license period.

Research and development

Costs related to internal research and development programs and fees for service and milestone payments paid to third parties are expensed as incurred.

Costs associated with revenue generated from research and development collaborations, and with providing contract research services are included in research and development expenses and were \$9,503,000, \$11,570,000 and \$7,596,000 in 2003, 2002 and 2001, respectively.

Acquired research and development

The costs of assets that are purchased through asset acquisitions or business combinations for a particular research and development project are expensed as acquired research and development at the time of acquisition. The amount allocated to acquired research and development is determined by identifying those specific in-process research and development projects that the Company intends to continue, and for which: (i) technological feasibility had not been established at the date of acquisition; and (ii) there was no alternative future use.

The efforts required to develop the acquired research and development into commercially viable products include the completion of the development stages of these projects, clinical-trial testing, regulatory approval and commercialization. The principal risks relating to these projects include the outcomes of the formulation development, clinical studies and regulatory filings. Since pharmaceutical products cannot be marketed without regulatory approvals, the Company will not receive any benefits unless regulatory approval is obtained. The completion of these projects may require significant amounts of future time and effort, as well as additional development costs, which may be incurred by the Company. Consequently, there is significant technological and regulatory approval risk associated with these projects at the date of acquisition.

The research being undertaken on these projects relates specifically to developing novel formulations of the associated molecules. Consequently, the Company does not foresee any alternative future benefit from the acquired research and development other than specifically related to these projects.

The fair value of acquired research and development is determined using an income approach on a project-by-project basis. The estimated future net cash flows related to these projects include the costs to develop these projects into commercially viable products, and the projected revenues to be earned on commercialization of these projects when complete. The discount rates used to present value the estimated future net cash flows related to each of these projects are determined based on the relative risk of achieving each of these project's net cash flows. The discount rates reflect the project's stage of completion and other risk factors, which include the nature and complexity of the product, the projected costs to complete, market competition and the estimated life of the product.

Advertising

Advertising costs related to new product launches are expensed on the first showing of the product. The Company did not have any deferred advertising costs at December 31, 2003. Deferred advertising costs of \$8,866,000 were included in deposits and prepaid expenses at December 31, 2002.

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 20-F

Advertising costs expensed in 2003, 2002 and 2001 were \$23,013,000, \$18,795,000 and \$3,957,000, respectively. These costs are included in selling, general and administrative expenses.

Co-promotion fees

Co-promotion fees payable by the Company to its co-promotion partner were accrued based on a percentage of the net sales of the co-promoted products. Co-promotion fees were included in selling, general and administrative expenses.

Stock-based compensation

Under the provisions of SFAS No. 123, "Accounting for Stock-Based Compensation", companies can either measure the compensation cost of equity instruments issued under employee compensation plans using a fair value-based method or can continue to recognize compensation cost using the intrinsic value-based method under the provisions of Accounting Principles Board Opinion ("APB") No. 25, "Accounting for Stock Issued to Employees". However, if the provisions of APB No. 25 are applied, pro forma disclosure of net income or loss and earnings or loss per share must be presented in the financial statements as if the fair value-based method had been applied.

The Company recognizes employee stock-based compensation costs under the intrinsic value-based method of APB No. 25. Accordingly, no compensation expense for stock options granted to employees at fair market value was recognized in net income or loss in 2003, 2002 or 2001; however, the Company recorded compensation expense in these years for stock options granted (at the date of acquisition) to the employees of DJ Pharma, Inc. ("DJ Pharma"). The following table presents the Company's pro forma net income or loss and earnings or loss per share as if the fair value-based method of SFAS No. 123 had been applied for all stock options granted:

	<u>2003</u>	<u>2002</u>	<u>2001</u>
Net income (loss) as reported	\$ (27,265)	\$ 87,795	\$ 87,448
Total pro forma stock-based compensation expense determined under fair value-based method	(16,903)	(14,254)	(12,216)
Pro forma net income (loss)	(44,168)	73,541	75,232
Basic earnings (loss) per share			
As reported	(0.17)	0.58	0.64
Pro forma	(0.28)	0.48	0.55
Diluted earnings (loss) per share			
As reported	(0.17)	0.55	0.58
Pro forma	(0.28)	0.46	0.50

The weighted average fair values of all stock options granted during 2003, 2002 and 2001 were \$11.48, \$13.58 and \$15.34, respectively, estimated as of the date of grant using the Black-Scholes option-pricing model with the following weighted average assumptions:

	<u>2003</u>	<u>2002</u>	<u>2001</u>
Expected option life (years)	4.0	3.8	4.0
Volatility	54.7%	46.8%	36.9%
Risk-free interest rate	3.9%	4.5%	5.2%
Dividend yield	%	%	%

The Black-Scholes option-pricing model used by the Company to calculate option values, as well as other currently accepted option valuation models, were developed to estimate the fair value of freely tradeable, fully transferable options without vesting restrictions, which significantly differ from the Company's stock option awards. These models also require highly subjective assumptions, including future stock price volatility and expected time until exercise, which greatly affect the calculated values.

Income taxes

Income taxes are accounted for under the liability method. Deferred tax assets and liabilities are recognized for the differences between the financial statement and income tax bases of assets and liabilities, and for operating losses and tax credit carryforwards. A valuation

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 20-F

allowance is provided for the portion of deferred tax assets that is more likely than not to remain unrealized. Deferred tax assets and liabilities are measured using enacted tax rates and laws.

Earnings or loss per share

Basic earnings or loss per share are calculated by dividing net income or loss by the weighted average number of common shares outstanding during the reporting period. Diluted earnings or loss per share are calculated by dividing net income or loss by the weighted average number of common shares outstanding during the reporting period after giving effect to dilutive potential common shares. The dilutive effects of stock options and warrants are determined using the treasury stock method. The dilutive effects of convertible securities are determined using the if-converted method.

Comprehensive income or loss

Comprehensive income or loss comprises net income or loss and other comprehensive income or loss. Other comprehensive income or loss comprises foreign currency translation adjustments and unrealized holding gains or losses on available-for-sale investments. Accumulated other comprehensive income or loss is recorded as a component of shareholders' equity.

Recent accounting pronouncements

In December 2002, the FASB issued SFAS No. 148, "Accounting for Stock-Based Compensation - Transition and Disclosure". SFAS No. 148 amends SFAS No. 123 to provide alternative methods of transition to SFAS No. 123's fair value-based method of accounting for stock-based employee compensation. SFAS No. 148 also amends the disclosure provisions of SFAS No. 123 and APB No. 28, "Interim Financial Reporting", to require disclosure in the summary of significant accounting policies of the effects of an entity's accounting policy with respect to stock-based employee compensation on reported net income and earnings per share in annual and interim financial statements. SFAS No. 148 is effective for fiscal years ending after December 15, 2002. The Company elected to continue to use the intrinsic value-based method under the provisions of APB No. 25, and adopted the required disclosures of SFAS No. 148 effective December 31, 2002.

In January 2003 (as amended in December 2003), the FASB issued FASB Interpretation ("FIN") No. 46, "Consolidation of Variable Interest Entities". FIN No. 46 requires consolidation of a variable interest entity ("VIE") by the primary beneficiary of the entity's expected results of operations. FIN No. 46 also requires certain disclosures by all holders of a significant variable interest in a VIE that are not the primary beneficiary. FIN No. 46 is effective immediately for VIEs created or acquired after January 31, 2003. For VIEs created or acquired prior to February 1, 2003, FIN No. 46 is effective in the first reporting period ending after December 31, 2003 for those VIEs that are considered to be special purpose entities, and after March 15, 2004 for those VIEs that are not considered to be special purpose entities. The adoption of FIN No. 46 had no effect on the Company's financial position or results of operations.

3. ACQUISITIONS

2003 acquisitions of intangible assets

During 2003, the Company acquired the following intangible assets. Total consideration related to each of these acquisitions was allocated based on the estimated fair values of the acquired assets on the respective dates of acquisition:

	Tramadol FT products	Ativan® and Isordil®	Athpharma products	Generic omeprazole	Other	Total
Acquired assets						
Acquired research and development	\$ 16,000	\$ 38,100	\$ 44,200	\$	\$	\$ 98,300
Trademarks		107,542				107,542
Product rights		16,041		35,500	256	51,797
Technology		2,156				2,156
	\$ 16,000	\$ 163,839	\$ 44,200	\$ 35,500	\$ 256	\$ 259,795

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 20-F

Consideration																		
Cash paid	\$	16,000	\$	146,342	\$	44,200	\$	35,500	\$	256	\$	242,298						
Long-term obligation				17,497								17,497						
		<u>\$</u>		<u>16,000</u>		<u>\$</u>		<u>163,839</u>		<u>\$</u>		<u>44,200</u>	<u>\$</u>	<u>35,500</u>	<u>\$</u>	<u>256</u>	<u>\$</u>	<u>259,795</u>

Tramadol FT products

In April 2002, Biovail acquired a 15% equity interest in Ethypharm S.A. ("Ethypharm") and obtained the rights to market six products under development by Ethypharm (as described in note 7 Long-Term Investments and note 22 Research and Development Collaborations). The products under development included Ethypharm's Flashtab versions of tramadol ("Tramadol FT") and combination of tramadol and acetaminophen ("Tramadol/Acetaminophen FT").

September 2003 agreements

In September 2003, Biovail entered into several agreements with Ethypharm relating to: (i) the acquisition of Ethypharm's remaining interest in Tramadol FT (including all relevant patents) and the elimination of Biovail's obligation to make any future milestone payments (except for a \$1,000,000 milestone payment if Tramadol FT is approved by the U.S. Food and Drug Administration ("FDA")) or royalty payments to Ethypharm related to Tramadol FT; (ii) the grant to Ethypharm of a 15-year license to manufacture and market Biovail's controlled-release formulation of diltiazem hydrochloride ("HCl") ("Diltiazem CR"), which is marketed by Biovail in the United States under the trade name Cardizem® LA, in all the countries of the world excluding Canada and the United States; (iii) the supply to Ethypharm of a quantity of diltiazem beads to enable it to encapsulate Diltiazem CR until the necessary technology transfer to manufacture diltiazem beads had been effected; and (iv) the grant to Ethypharm of a right to market Biovail's once-daily formulation of bupropion HCl in all countries outside of North America not elected by GlaxoSmithKline plc ("GSK") pursuant to the Wellbutrin XL agreement between Biovail and GSK (as described in note 21 Co-Promotion and License Arrangements).

In September 2003, Biovail accounted for these transactions on a net basis, reflecting that these agreements were negotiated and concluded almost simultaneously. Biovail recorded a net charge to acquired research and development of \$3,063,000 related to these agreements, reflecting the following amounts that were contractually agreed to by the parties, as well as the cost of the diltiazem beads supplied to Ethypharm:

Tramadol FT acquisition	\$	21,000
Diltiazem CR proceeds		(20,000)
Cost of diltiazem beads supplied		<u>2,063</u>
Acquired research and development	<u>\$</u>	<u>3,063</u>

Biovail also agreed, subject to certain conditions, to subscribe for up to \$20,000,000 of convertible and/or exchangeable bonds of Ethypharm. Certain of the conditions precedent to the closing of the bond subscription agreement required third parties, independent of Ethypharm and Biovail, to agree to revisions to their existing agreements with Ethypharm.

Biovail also negotiated with Ethypharm for significant improvements to the shareholder agreement, providing equity protection for an indefinite period of time on Biovail's initial investment in Ethypharm in the event of any private or public financing undertaken by Ethypharm.

February 2004 amendments

In February 2004, Biovail and Ethypharm agreed to amend the September 2003 agreements as follows:

The purchase price for Tramadol FT was reduced from \$21,000,000 to \$16,000,000. Biovail remains obligated to pay Ethypharm a \$1,000,000 milestone payment if Tramadol FT is approved by the FDA. In addition to Tramadol FT, Biovail acquired Ethypharm's remaining interest in Tramadol/Acetaminophen FT (including all relevant patents). Biovail will pay Ethypharm a royalty on any future sales of Tramadol/Acetaminophen FT.

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 20-F

The Diltiazem CR license agreement was terminated (including the supply of diltiazem beads), as was the bond subscription agreement. In addition, the term of the equity protection on Biovail's initial investment in Ethypharm was reduced from an indefinite period of time to 18 months. The grant to Ethypharm of a right to market Wellbutrin XL in all countries outside North America was effectively nullified by GSK's subsequent election to develop and market Wellbutrin XL on a worldwide basis.

The February 2004 amendments confirmed conditions that existed at the date of the consolidated financial statements and, accordingly, Biovail recorded these amendments effective December 31, 2003. The effect of these amendments on the original accounting for the September 2003 transactions was as follows: (i) the proceeds from the sales of the Diltiazem CR license and the diltiazem beads were reversed; (ii) the cost of the diltiazem beads was returned to inventory; and (iii) the charge to acquired research and development was increased from \$3,063,000 to \$16,000,000 to reflect the actual cash paid for Tramadol FT and Tramadol /Acetaminophen FT pursuant to the February 2004 amendments.

Acquired research and development

At the dates of acquisition, Tramadol FT was in a late-stage clinical phase of development and Tramadol/Acetaminophen FT was in a pre-clinical phase of development. At the dates of acquisition, neither of these products had been submitted for approval by the FDA. In March 2004, Biovail filed a New Drug Application ("NDA") with the FDA for Tramadol FT (Ralivia FlashDose®).

Ativan® and Isordil®

In May 2003, Biovail acquired from Wyeth Pharmaceuticals Inc. ("Wyeth") the rights to Ativan® (lorazepam), indicated for the management of anxiety disorders, and Isordil® (isosorbide dinitrate), indicated for the prevention of angina pectoris due to coronary artery disease, in the United States. Biovail also acquired a license to use certain technologies relating to Wyeth's Canadian sublingual version of Ativan® to develop new Ativan® line extension products to be sold in the United States. Wyeth will manufacture and supply Ativan® and Isordil® to Biovail for three years from the date of acquisition. Biovail will make two fixed annual payments of \$9,150,000 each to Wyeth under the manufacturing and supply agreement (regardless of the actual product supplied). Biovail will also pay Wyeth royalties on any future sales of any Ativan® line extension products that may be developed and marketed by Biovail, as well as a \$20,000,000 additional rights payment, increasing at 10% per annum, on the approval by the FDA of the first Ativan® line extension product that may be developed by Biovail.

The purchase price for Ativan® and Isordil® was \$163,839,000 comprising cash consideration, including costs of acquisition, of \$146,342,000, and the two remaining fixed annual payments. The remaining fixed annual payments were present valued using an imputed interest rate of 3.00%, which was comparable to Biovail's available borrowing rate at the date of acquisition. Accordingly, the present value of the remaining fixed annual payments was determined to be \$17,497,000.

The fair values of the acquired assets were determined using an income approach. The discount rates used to present value the estimated future cash flows related to each acquired asset were determined based on the relative risk of achieving each asset's estimated future cash flows and were in the range of 10.5% to 35%.

The trademarks are being amortized over their estimated useful lives of 20 years. The product rights and technology are being amortized over their estimated useful lives of 15 years. The estimated weighted average useful life of the trademarks, product rights and technology is approximately 19 years.

Acquired research and development

At the date of acquisition, the Ativan® line extension products were in pre-clinical phases of development, and none of these products had been submitted for approval by the FDA. The discount rates used to present value the estimated future cash flows related to these products were in the range of 30% to 35%. The costs to complete the development of these products are estimated to be up to \$23,500,000.

Athpharma products

In April 2003, Biovail entered into an agreement with Athpharma Limited ("Athpharma") to acquire four cardiovascular products under development for \$44,200,000, including costs of acquisition. The four products under development are Bisochron (bisoprolol), a beta-1 selective beta-blocker formulation for the treatment of hypertension, Isochron (isosorbide-5-mononitrate), a long acting nitrate formulation for the treatment of angina, and Hepacol I (pravastatin) and Hepacol II (simvastatin), two liver-selective statin formulations for the treatment of high cholesterol. Athpharma will complete the development of these products. Biovail will pay a

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 20-F

portion of the development costs, and may make aggregate payments of \$24,200,000 to Athpharma subject to the attainment of certain milestones. Biovail will also pay Athpharma royalties on any future sales of these products.

Acquired research and development

At the date of acquisition, Bisochron and Isochron were both entering Phase III clinical studies, and Hepacol I and Hepacol II were both in pre-clinical phases of development, and none of these products had been submitted for approval by the FDA. The discount rates used to present value the estimated future cash flows related to these products were in the range of 45% to 70%. The following values were assigned to these products:

Bisochron \$21,550,000, Isochron \$13,100,000, Hepacol I \$6,985,000 and Hepacol II \$2,565,000. Biovail's share of the costs to complete the development of these products is estimated to be \$20,000,000.

Generic omeprazole

In May 2003, Biovail paid \$35,500,000 to the previous owners of Pharma Pass LLC (a company acquired by Biovail in December 2002, as described below under 2002 acquisitions of businesses) related to an additional participating interest in the gross profit on sales of generic omeprazole owned by those parties. Amortization of \$34,379,000 related to the cost of this acquired asset was recorded in 2003, as Biovail had received most of the value from this participating interest by December 31, 2003.

2002 acquisitions of intangible assets

During 2002, the Company acquired the following intangible assets. Total consideration related to each of these acquisitions was allocated based on the estimated fair values of the acquired assets on the respective dates of acquisition:

	Wellbutrin® and Zyban®	Vasotec® and Vaseretic®	Teveten®	Zovirax	Total
Acquired assets					
Prepaid expenses	\$ 2,609	\$	\$	\$	\$ 2,609
Trademarks	24,349	165,804			190,153
Product rights	45,000	79,500	94,340	173,364	392,204
	\$ 71,958	\$ 245,304	\$ 94,340	\$ 173,364	\$ 584,966
Consideration					
Cash paid, net of gross profit on acquired assets	\$ 1,997	\$ 145,684	\$ 94,340	\$ 133,364	\$ 375,385
Long-term obligations	69,961	99,620		40,000	209,581
	\$ 71,958	\$ 245,304	\$ 94,340	\$ 173,364	\$ 584,966

Wellbutrin® and Zyban®

In December 2002, Biovail acquired from GSK the rights to Wellbutrin® SR and Zyban® in Canada. Biovail also acquired the right to market its once-daily formulation of bupropion HCl in Canada under the trade name Wellbutrin® XL if regulatory approval is received. Wellbutrin® SR is prescribed for the treatment of depression and Zyban® is administered for the treatment of nicotine addiction as an aid to smoking cessation. Both products are formulations of bupropion HCl. Biovail obtained the beneficial rights to Wellbutrin® SR and Zyban® effective December 1, 2002, and obtained full legal rights on March 2, 2004, following the completion of the payments described below.

GSK will continue to manufacture and supply Wellbutrin® SR and Zyban® to Biovail for four years from the date of acquisition. GSK will assist in qualifying a Biovail facility to achieve the transition of the manufacturing process. GSK continued to market Wellbutrin® SR and Zyban® in Canada during the period from December 1, 2002 to December 31, 2003 and, in consideration, Biovail paid GSK a tiered royalty on the net sales of these products during this period. Biovail will also pay GSK a royalty on any future sales of Wellbutrin® XL in Canada for a period of 20 years from the date of commercial launch of this product.

The purchase price for Wellbutrin® and Zyban® comprised cash consideration, including costs of acquisition, of \$3,320,000, less GSK's gross profit on the acquired assets from December 1, 2002 (the effective date of the transaction) to December 26, 2002 (the closing date of the transaction) of \$1,323,000, plus remaining payments of \$72,072,000 payable in four quarterly instalments from June 1, 2003 to

March 1, 2004. These payments were present valued using an imputed interest rate of 3.74%, which was comparable to Biovail's available borrowing rate at the date of the transaction. Accordingly, the present value of these payments was determined to be \$69,961,000.

The prepaid expenses were amortized over a one-year period from January 1, 2003. These expenses related to the minimum amount that GSK committed to spend on the marketing of Wellbutrin® SR and Zyban® in Canada during that period. The trademarks and product rights are being amortized over their estimated useful lives of 20 years and 15 years, respectively. The estimated weighted average useful life of the acquired assets is approximately 16 years.

Vasotec® and Vaseretic®

In May 2002, Biovail acquired from Merck & Co., Inc. ("Merck") the rights to Vasotec® (enalapril) and Vaseretic® (enalapril and hydrochlorothiazide combination) in the United States. Vasotec® and Vaseretic® are prescribed for the treatments of hypertension and congestive heart failure. Biovail also acquired the fixed-dose combination NDA of enalapril in combination with diltiazem malate. Merck will continue to manufacture and supply Vasotec® and Vaseretic® to Biovail for five years from the date of acquisition. Biovail will make semi-annual payments to Merck over a five-year term for minimum product quantities and a minimum fixed royalty (regardless of the actual product supplied). Biovail will also pay Merck royalties on any future sales of any life cycle products developed and marketed in the United States.

Biovail also entered into a separate agreement with Merck to develop, license and supply a new dosage format of a Merck product under development (as described in note 22 Research and Development Collaborations).

The purchase price for Vasotec® and Vaseretic® comprised cash consideration, including costs of acquisition, of \$155,634,000, less Merck's gross profit on the acquired assets from April 1, 2002 (the effective date of the transaction) to May 10, 2002 (the closing date of the transaction) of \$9,950,000, plus the minimum fixed royalty payments required to be made by Biovail to Merck of \$109,276,000. These payments were present valued using an imputed interest rate of 5.75%, which was comparable to Biovail's available borrowing rate at the date of the transaction. Accordingly, the present value of these payments was determined to be \$99,620,000.

The trademarks and product rights are being amortized over their estimated useful lives of 20 years and 15 years, respectively. The estimated weighted average useful life of the acquired assets is approximately 19 years.

A letter of credit was issued to Merck to secure the remaining semi-annual payments Biovail is required to make under the Vasotec® and Vaseretic® agreement. The letter of credit was issued under Biovail's revolving term credit facility, and had a balance remaining of \$61,207,000 and \$93,170,000 at December 31, 2003 and 2002, respectively. The fees incurred to issue the letter of credit are amortized to interest expense over the related term of the letter of credit.

Teveten®

In March 2002, Biovail acquired from Solvay Pharmaceuticals Marketing & Licensing AG ("Solvay") the rights to Teveten® (eprosartan mesylate) and Teveten® HCT (eprosartan mesylate and hydrochlorothiazide combination) in the United States. Teveten® is an angiotensin-II receptor blocker for the treatment of hypertension and is indicated for use either alone or in conjunction with other antihypertensive medications.

The purchase price for Teveten® comprised cash consideration of \$94,340,000, including costs of acquisition. The product rights are being amortized over their estimated useful life of 20 years.

Solvay will continue to manufacture and supply Teveten® and Teveten® HCT to Biovail for up to 12 years from the date of acquisition, and will assist in qualifying a Biovail facility to achieve the transition of the manufacturing process. Solvay will continue to manufacture and market Teveten® and Teveten® HCT in areas outside of the United States. Solvay paid Biovail a \$20,000,000 marketing allowance to reimburse Biovail for the agreed upon direct costs related to the re-launch and marketing of Teveten® and Teveten® HCT in the United States. Biovail recorded one-half of the marketing allowance each year in 2003 and 2002 as a reduction of selling, general and administrative expenses. Biovail formed a joint business development committee with Solvay to discuss future clinical and product development options that could enhance the performance or expand the utilization of Teveten®. Solvay has the option to acquire, for worldwide markets excluding the United States, all potential future modifications and innovations developed by Biovail for Teveten®.

Zovirax

Effective January 1, 2002, Biovail acquired from GSK the exclusive distribution rights for Zovirax (acyclovir) Ointment and Zovirax Cream in the United States. Zovirax is a topical anti-viral product. Zovirax Ointment is indicated for the treatment of herpes, and Zovirax Cream is indicated for the treatment of cold sores. GSK will continue to manufacture and supply Zovirax Ointment and Zovirax Cream to Biovail over the term of the distribution agreement.

The purchase price for Zovirax comprised cash consideration of \$133,364,000, including costs of acquisition. The product rights were being amortized over their estimated useful life of 10 years, based on the original term of the distribution agreement.

In the event of the termination of the Wellbutrin XL agreement (as described in note 21 Co-Promotion and License Arrangements) by either Biovail or GSK, Biovail would be required to pay GSK additional payments for the rights to Zovirax of \$22,000,000 per year in calendar years 2004 through 2006, and in calendar years 2007 through 2011, Biovail would be required to pay GSK additional payments based on a percentage of Biovail's gross sales of Zovirax during the immediately preceding calendar year.

Effective October 1, 2002, Biovail amended several terms of the original Zovirax distribution agreement with GSK, including a reduction in the supply price for this product. Biovail has been paying the reduced Zovirax supply price since the effective date; however, the reduction in the supply price was subject to repayment if Wellbutrin XL was not approved by the FDA. Accordingly, Biovail had been deferring the value of the reduction in the supply price in accrued liabilities pending the outcome of the Wellbutrin XL approval. In June 2003, GSK received an approvable letter relating to Wellbutrin XL, which raised only routine matters. As a result, Biovail believed that the likelihood of repaying the reduction in the supply price was low and, accordingly, Biovail reversed the accrued liability for the deferred value of the reduction in the supply price. The recognition of the aggregate deferred value of \$25,456,000, as of the date of the approvable letter, was recorded as a reduction to the cost of Zovirax sold in 2003. In August 2003, GSK received FDA approval for Wellbutrin XL.

In December 2002, Biovail and GSK agreed to a 10-year extension of the Zovirax distribution agreement. In consideration for this extension, Biovail paid GSK \$40,000,000 in March 2003. This amount was added to the value of the unamortized Zovirax product rights and, subsequent to the date of amendment, these product rights are being amortized over their revised estimated remaining useful life of 19 years.

2003 acquisition of business**BNC-PHARMAPASS****Description of acquisition**

In July 2003, Biovail and Pharma Pass II, LLC ("PPII") formed BNC-PHARMAPASS, LLC ("BNC-PHARMAPASS") to advance the development of three products. These products were carvedilol (Coreg), a beta-blocker indicated for the treatment of congestive heart failure, tamsulosin (Flomax), indicated for the treatment of benign prostatic hyperplasia, and eprosartan (Teveten®). On the formation of BNC-PHARMAPASS, PPII contributed all of its intellectual property relating to these products, which was fair valued at an amount of \$31,350,000, for a 51% interest in this company, and Biovail contributed cash in the amount of \$30,060,000, for a 49% interest in this company. PPII agreed to complete the formulation work in connection with these products. Biovail agreed to pay the cost of all clinical trials and certain other development costs related to these products. Biovail had an option to acquire PPII's interest in BNC-PHARMAPASS for cash consideration plus a royalty on any future sales of these products.

Subsequent to date of formation, PPII reduced its capital in BNC-PHARMAPASS through the withdrawal of \$25,741,000 of cash from BNC-PHARMAPASS. As a result, PPII's interest in BNC-PHARMAPASS was reduced to 16%, and Biovail's interest in BNC-PHARMAPASS increased to 84% at December 31, 2003.

BNC-PHARMAPASS has been consolidated in these financial statements from the date of formation. At December 31, 2003, Biovail's investment in BNC-PHARMAPASS was recorded in these financial statements as follows:

Cash	\$ 4,319
Minority interest	(679)
Acquired research and development	26,420
	<hr/>
Cash contributed	\$ 30,060
	<hr/>

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 20-F

Subsequent to December 31, 2003, PPII further reduced its interest in BNC-PHARMAPASS through a withdrawal of cash from BNC-PHARMAPASS, and Biovail exercised its option to acquire PPII's remaining interest in BNC-PHARMAPASS in February 2004 (as described in note 28 Subsequent Events).

Acquired research and development

At the dates of acquisition, the carvedilol, tamsulosin and eprosartan products were in pre-formulation and formulation phases of development, and none of these products had been submitted for approval by the FDA. The discount rates used to present value the estimated future cash flows related to these products were in the range of 30% to 45%. The costs to complete the development of these products are estimated to be \$50,000,000.

2002 acquisitions of businesses

During 2002, Biovail completed the acquisitions of Pharmaceutical Technologies Corporation ("Pharma Tech") and Pharma Pass LLC and Pharma Pass S.A. (collectively, "Pharma Pass"). These acquisitions were accounted for under the purchase method of accounting. Total consideration, including costs of acquisition, was allocated based on the estimated fair values of the acquired assets on the respective dates of acquisition as follows:

	Pharma Tech	Pharma Pass	Total
Acquired assets			
Acquired research and development	\$ 60,558	\$ 107,187	\$ 167,745
Product rights	5,000	63,800	68,800
Technology		7,700	7,700
Current liabilities	(3,664)		(3,664)
	\$ 61,894	\$ 178,687	\$ 240,581
Consideration, net of cash acquired			

Pharma Tech

Background

Pharma Tech was a development-stage company engaged in the application of drug delivery technologies to the formulation and development of a portfolio of products. Pharma Tech contracted directly with third parties, including Biovail, to conduct the contract research and development services. Biovail provided contract research and advisory services consistent with contractual relationships it had with other third parties. On the completion of the development of Biovail's products, Biovail had the right to manufacture and sell the products and Pharma Tech was entitled to royalties from the net sales of each product for a period of 10 years from the date of launch of each product. Biovail had options to acquire Pharma Tech's interest in the products or to acquire Pharma Tech.

Prior to the acquisition, Biovail earned revenue from providing advisory and contract research services to Pharma Tech of \$2,844,000 and \$2,189,000 in 2002 and 2001, respectively. The costs of providing these services to Pharma Tech were \$2,053,000 and \$1,679,000 in 2002 and 2001, respectively, and Biovail was reimbursed amounts at cost of \$2,509,000 and \$1,395,000 in 2002 and 2001, respectively. In 2002, Biovail also recorded \$6,689,000 of up-front fees in research and development revenue. These fees had been received from Pharma Tech in 2001, at which time they were deferred for subsequent amortization to revenue. The deferred revenue was fully amortized at December 31, 2002.

Description of acquisition

On December 17, 2002, Biovail paid \$43,080,000 to Pharma Tech to terminate the development by Pharma Tech of one of the products under development and the associated royalties on future sales of this product if approved by the FDA. At the date of termination, this product had not been submitted for approval by the FDA. Accordingly, the termination payment was expensed as acquired research and development. Biovail is continuing the development program for this product.

On December 31, 2002, Biovail acquired 100% of the outstanding shares of Pharma Tech for \$22,600,000, including costs of acquisition. Through the acquisition of Pharma Tech, Biovail extinguished any future milestone or royalty obligations that Biovail may have had to Pharma Tech resulting from the approval and successful commercialization of any of the products under development, pursuant to the

research and development agreements previously entered into between Biovail and Pharma Tech. Pharma Tech has been included in Biovail's consolidated financial statements from the date of acquisition.

The acquired assets of Pharma Tech were fair valued using an income approach. The discount rates used to present value the estimated future cash flows related to each asset were determined based on the relative risk of achieving each asset's estimated future cash flows and were in the range of 30% to 45%.

Acquired research and development

At the date of acquisition, Pharma Tech was involved in a number of product development projects that were in various stages of completion and had not been submitted for approval by the FDA. Subsequent to the date of acquisition, Biovail discontinued one of these projects but is continuing the development programs for the remaining products.

At the date of acquisition, an additional product development project had received an approvable letter from the FDA; however, significant technical issues required resolution before final approval would be granted. Therefore, the technological feasibility of this project had not been established at the date of acquisition. Biovail is continuing to work to resolve these issues.

Product rights

At the date of acquisition, Pharma Tech was involved with a product development project that had been submitted for approval by the FDA. This product has received an approvable letter from the FDA, which raised only routine matters. Biovail believes that these matters can be successfully resolved and that final approval will be granted. However, since pharmaceutical products cannot be marketed without regulatory approvals, Biovail will not receive any benefits until regulatory approval is obtained. The product rights are being amortized over their estimated useful life of 15 years.

Pro forma information (unaudited)

The following unaudited pro forma information presents a summary of the consolidated results of operations of Biovail and Pharma Tech as if the acquisition had occurred on January 1, 2001. Included in the consolidated results for 2001 is the charge for acquired research and development. All transactions between Biovail and Pharma Tech have been eliminated.

	<u>2002</u>	<u>2001</u>
Total revenue	\$ 778,492	\$ 579,815
Net income	105,741	5,411
Basic earnings per share	\$ 0.70	\$ 0.04
Diluted earnings per share	\$ 0.66	\$ 0.04

These unaudited pro forma consolidated results have been prepared for comparative purposes only. They do not purport to be indicative of the results of operations that actually would have resulted had Pharma Tech been included in Biovail's consolidated financial statements from January 1, 2001. In addition, they do not purport to be indicative of future consolidated results of operations of Biovail.

PHARMA PASS

Background

Pharma Pass was a developer of advanced oral controlled-release technologies and formulations for pharmaceutical companies, including Biovail, in Europe and the United States. On the completion of the development of Biovail's products, Biovail had the right to manufacture and sell the products and Pharma Pass was entitled to royalties from the net sales of each product for a period of 15 years from the date of launch of each product.

Description of acquisition

On December 6, 2002, Biovail acquired 100% of the outstanding interests of Pharma Pass LLC and 100% of the outstanding shares of Pharma Pass S.A. for \$178,687,000, including costs of acquisition. Through the acquisition of Pharma Pass, Biovail extinguished any future milestone or royalty obligations that Biovail may have had to Pharma Pass resulting from the approval and successful

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 20-F

commercialization of any of the products under development, pursuant to the research and development agreements previously entered into between Biovail and Pharma Pass. Pharma Pass has been included in Biovail's consolidated financial statements from the date of acquisition.

The acquired assets of Pharma Pass were fair valued using an income approach. The discount rates used to present value the estimated future cash flows related to each asset were determined based on the relative risk of achieving each asset's estimated future cash flows and were generally in the range of 9% to 45%. The estimated weighted average useful life of the acquired assets is approximately four years.

Acquired research and development

At the date of acquisition, Pharma Pass was involved in approximately 20 product development projects for a number of pharmaceutical companies including Biovail. At the date of acquisition, a number of these products had been submitted for approval by the FDA. Subsequent to the date of acquisition, one of these products received FDA approval.

The remaining products were in various stages of completion, and are expected to be submitted for approval by the FDA, and/or other regulatory authorities, over approximately the succeeding three years. Biovail is continuing the development programs for these products.

Product rights

Biovail obtained interests in certain licensed products including Tricor (fenofibrate) and generic omeprazole. Biovail is entitled to royalties on sales of Tricor and a participating interest in the gross profit on sales of generic omeprazole.

The interest in Tricor is being amortized over its estimated useful life of eight years. The cost of the generic omeprazole acquired asset was fully amortized in 2003, as Biovail had received all of the value of this participating interest by December 31, 2003.

Technology

Biovail obtained the patents related to Pharma Pass's Zero Order Release System ("ZORS"), a drug delivery technology that controls the rate of release of a drug and/or significantly enhances the systemic absorption of a drug molecule. Biovail believes the ZORS technology has application to products currently in formulation and to the future development of controlled-release products.

Biovail also obtained Pharma Pass's oral Colonic Delivery System, a drug delivery technology designed for the targeted release of medication into the lower intestine and upper colon. Biovail also has the option to continue the development of four products utilizing this technology. Biovail will pay up to \$10,000,000 in milestone fees subject to the successful completion of the development of these products. Biovail will obtain ownership of the related patents following the net payment of \$10,000,000 less the sum of the milestone fees paid.

The technology is being amortized over its estimated useful life of 15 years.

Pro forma information (unaudited)

The following unaudited pro forma information presents a summary of the consolidated results of operations of Biovail and Pharma Pass as if the acquisition had occurred on January 1, 2001. Included in the consolidated results for 2001 is the charge for acquired research and development. All transactions between Biovail and Pharma Pass have been eliminated.

	2002	2001
Total revenue	\$ 794,827	\$ 587,408
Net income (loss)	198,004	(19,672)
Basic earnings (loss) per share	\$ 1.30	\$ (0.14)
Diluted earnings (loss) per share	\$ 1.23	\$ (0.14)

These unaudited pro forma consolidated results have been prepared for comparative purposes only. They do not purport to be indicative of the results of operations that actually would have resulted had Pharma Pass been included in Biovail's consolidated financial statements from January 1, 2001. In addition, they do not purport to be indicative of future consolidated results of operations of Biovail.

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 20-F

4. CASH AND CASH EQUIVALENTS

	<u>2003</u>	<u>2002</u>
Cash and bank certificates of deposit	\$ 72,928	\$ 39,111
Money market funds and corporate debt securities	54,914	16,969
Canadian and U.S. government securities	5,419	
	<u>\$ 133,261</u>	<u>\$ 56,080</u>

The Company invests its excess cash in high-quality (investment grade 'AA' or better) money market, and government and corporate debt securities.

5. ACCOUNTS RECEIVABLE

	<u>2003</u>	<u>2002</u>
Trade	\$ 159,656	\$ 144,748
Less allowances for doubtful accounts and sales discounts	3,954	3,440
	<u>155,702</u>	<u>141,308</u>
Royalties	16,089	30,104
Other	7,583	19,568
	<u>\$ 179,374</u>	<u>\$ 190,980</u>

The four largest customer balances accounted for 55% of trade and royalties receivables at December 31, 2003. The four largest customer balances accounted for 53% of trade and royalties receivables at December 31, 2002. The Company believes that there is no unusual exposure associated with the collection of these receivables.

6. INVENTORIES

	<u>2003</u>	<u>2002</u>
Raw materials	\$ 25,937	\$ 14,949
Work in process	26,803	11,901
Finished goods	31,318	26,197
	<u>\$ 84,058</u>	<u>\$ 53,047</u>

7. LONG-TERM INVESTMENTS

	<u>2003</u>	<u>2002</u>
Ethypharm	\$ 67,802	\$ 67,802
Depomed, Inc.	30,562	6,277
Reliant Pharmaceuticals, LLC	8,929	
Other	6,253	5,245
	<u>\$ 113,546</u>	<u>\$ 79,324</u>

Ethypharm

In April 2002, Biovail invested \$67,802,000, including costs of acquisition, to acquire 9,794,118 common shares (15% of the issued and outstanding common shares) of Ethypharm. In addition, Biovail obtained a three-year option to purchase up to 4,080,882 additional common shares of Ethypharm for \$6.66 per share plus 10% per annum, compounded annually. Biovail has not exercised its option. The investment in Ethypharm is being accounted

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 20-F

for using the cost method.

In September 2003 (as amended in February 2004), Biovail negotiated with Ethypharm for equity protection on its initial investment in Ethypharm in the event of any private or public financing undertaken by Ethypharm on or before June 9, 2005. Biovail is monitoring its

F-24

investment in Ethypharm, as Ethypharm will need to achieve certain improvements in operating performance or a write-down of this investment may become necessary.

Depomed, Inc. ("Depomed")

In July 2002, Biovail invested \$13,675,000, including costs of acquisition, to acquire 2,465,878 newly issued common shares (15% of the issued and outstanding common shares) of Depomed. In addition, Biovail obtained a one-year option to purchase up to 821,959 additional common shares of Depomed for \$5.125 per share. Biovail also obtained a three-year option to purchase additional common shares of Depomed, in an amount sufficient for Biovail to increase its investment up to 20% of Depomed's issued and outstanding common shares (calculated following the exercise of the option), for \$5.00 per share plus 20% per annum, compounded monthly. In July 2003, the one-year option expired unexercised. Biovail has not exercised its remaining three-year option.

In July 2002, Biovail also licensed the rights to manufacture and market Depomed's once-daily metformin HCl product ("Metformin GR") (as described in note 22 Research and Development Collaborations).

In April 2003, in connection with a private placement by Depomed, Biovail acquired an additional 1,626,154 common shares of Depomed for \$3,533,000. Biovail also obtained warrants to acquire 569,154 shares of Depomed, which are exercisable from July 2003 until April 2008 at an exercise price of \$2.16 per share.

The investment in Depomed has been classified as being available-for-sale. At December 31, 2003 and 2002, Biovail's investment represented approximately 12% and 15%, respectively, of the issued and outstanding common shares of Depomed. At December 31, 2003 and 2002, the fair values of this investment, based on quoted market prices, were \$30,562,000 and \$6,277,000, respectively. In 2002, Biovail recorded an unrealized holding loss of \$7,398,000 in net income to reflect an other than temporary decline in the value of this investment (as described in note 15 Write-Down of Assets). In 2003, in connection with an increase in the quoted market value of Depomed's common shares, Biovail recorded an unrealized holding gain of \$20,752,000 in comprehensive income to reflect an increase in the value of this investment. This holding gain will not be recorded in net income or loss until realized.

Reliant Pharmaceuticals, LLC ("Reliant")

In December 2003, in connection with the collection of its loan receivable from Reliant (as described in note 10 Other Assets), Biovail subscribed to \$8,929,000 of Series D Preferred Units of Reliant. These units are convertible on a 1:1 basis into Reliant's common units and are senior to all existing preferred classes of units (Series A, B and C) of Reliant. These units do not entitle the holders to a preferred return (or dividends). In the case of a liquidation of Reliant, these units are entitled to a distribution, before any other distribution or payment is made to any unit ranking junior to these units, of an amount equal to the sum of: (i) \$20.00 per unit; and (ii) interest on such amount at a rate of 8.5% per annum from the date of contribution. These units are redeemable by Reliant at a redemption price equal to the preceding amount. These units have voting rights equal to the number of whole common units into which they are convertible. At December 31, 2003, Biovail's investment in these units represented less than 2% of the issued and outstanding common and preferred units of Reliant. This investment is being accounted for using the cost method.

8. PROPERTY, PLANT AND EQUIPMENT

	2003		2002	
	Cost	Accumulated depreciation	Cost	Accumulated depreciation
Land	\$ 11,378	\$	\$ 10,477	\$
Buildings	75,186	9,742	59,341	6,959
Machinery and equipment	88,594	26,269	62,736	16,920
Other equipment and leasehold improvements	56,083	21,426	42,401	14,292
	<u>231,241</u>	<u>\$ 57,437</u>	<u>174,955</u>	<u>\$ 38,171</u>
Less accumulated depreciation	57,437		38,171	
	<u>\$ 173,804</u>		<u>\$ 136,784</u>	

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 20-F

At December 31, 2003 and 2002, the cost of property, plant and equipment included \$20,606,000 and \$54,365,000, respectively, of assets under construction or awaiting FDA approval and not available for productive use. Interest capitalized amounted to \$1,422,000 and \$513,000 in 2003 and 2002, respectively.

Depreciation expense amounted to \$15,351,000, \$9,794,000 and \$9,386,000 in 2003, 2002 and 2001, respectively.

9. INTANGIBLE ASSETS

	2003		2002	
	Cost	Accumulated amortization	Cost	Accumulated amortization
Trademarks	\$ 703,698	\$ 81,371	\$ 596,223	\$ 47,794
Product rights	550,880	141,068	571,105	55,531
Technology	21,041	3,705	18,885	2,385
	1,275,619	\$ 226,144	1,186,213	\$ 105,710
Less accumulated amortization	226,144		105,710	
	\$ 1,049,475		\$ 1,080,503	

Amortization expense amounted to \$139,357,000, \$72,574,000 and \$40,318,000 in 2003, 2002 and 2001, respectively. Estimated annual amortization expense, related to intangible assets recorded at December 31, 2003, for each of the five succeeding years ending December 31 is as follows:

2004	\$ 66,000
2005	65,000
2006	64,000
2007	64,000
2008	64,000

Product rights have an estimated weighted average useful life of approximately 16 years. Total intangible assets have an estimated weighted average useful life of approximately 18 years.

10. OTHER ASSETS

	2003	2002
Deferred financing costs	\$ 17,311	\$ 17,348
Less accumulated amortization	6,274	3,536
	11,037	13,812
Zovirax distribution agreement	40,656	40,656
Interest rate swaps	14,746	18,647
Deferred compensation trust fund	5,644	5,681
Loan receivable		30,000
Long-term receivable		4,554
Other	600	
	\$ 72,683	\$ 113,350

Amortization expense related to deferred financing costs amounted to \$2,975,000, \$2,267,000 and \$1,580,000 in 2003, 2002 and 2001, respectively.

Zovirax distribution agreement

In consideration for certain amendments to the original Zovirax distribution agreement with GSK, Biovail agreed to pay GSK \$11,250,000 per year in four annual instalments on March 31 of each year beginning in 2004. The annual instalment payments were present valued using an imputed interest rate of 3.74%, which was comparable to Biovail's available borrowing rate at the date of the transaction. Accordingly, the present value of these payments was determined to be \$40,656,000, which was recorded in other assets. This amount will be amortized over the period of benefit from the amended terms.

Interest rate swaps

The fair value of the Company's fixed rate 7⁷/₈% Senior Subordinated Notes due April 1, 2010 ("Notes") is affected by changes in interest rates. The Company manages this exposure to interest rate changes through the use of interest rate swaps, which are recorded at fair value in the Company's consolidated balance sheets. In June 2002, the Company entered into three interest rate swaps of aggregate \$200,000,000 notional amount, which were designated as a hedge of the Notes. These swaps involve the receipt of amounts based on a fixed rate of 7⁷/₈% in exchange for floating rate interest payments, based on six-month London Interbank Offering Rate ("LIBOR") plus a spread of 2.69% to 2.99%, without an exchange of the underlying principal amount. Net receipts or payments relating to these swaps are recorded as an adjustment to interest expense.

Prior to April 1, 2003, these swaps effectively modified the Company's exposure to interest rate fluctuations by converting the interest payable on one-half of the fixed rate Notes to a floating rate. The changes in the fair values of these swaps and the offsetting changes in the fair value of the portion of the Notes being hedged were recorded in other income or expense. Accordingly, the net gain or loss recognized prior to April 1, 2003 related to the ineffective portion of the fair value hedge.

Effective April 1, 2003, the Company determined that the hedging relationship no longer qualified as a highly effective hedge based on the dollar-offset method of testing hedge effectiveness as outlined in the Company's hedge documentation and, accordingly, the Company discontinued the application of hedge accounting as of that date. As a result, for the period from April 1, 2003 to September 30, 2003, these swaps continued to be adjusted for changes in their fair values; however, the Notes were not adjusted for the changes in their fair value during this period. The fair value adjustment to the Notes of \$15,129,000 at April 1, 2003, is being accreted to interest expense based on the remaining term of the Notes.

For the period from October 1, 2003 to December 5, 2003, the Company determined that the hedging relationship again qualified as a highly effective hedge based on the dollar-offset method of testing hedge effectiveness as outlined in the Company's hedge documentation and, accordingly, the Company reinstated the application of hedge accounting during this period. Effective December 5, 2003, the Company identified a new methodology of assessing the effectiveness of the fair value hedge based on regression analysis, and it redesignated the hedging relationship under this new method. For the period from December 5, 2003 to December 31, 2003, the Company determined that the hedging relationship qualified as a highly effective hedge based on the new method of testing hedge effectiveness as outlined in the Company's revised hedge documentation and, accordingly, the Company applied hedge accounting during this period.

The marked-to-market values of the interest rate swaps at December 31, 2003 and 2002 of \$14,746,000 and \$18,647,000, respectively, were recorded in other assets, with offsetting fair value adjustments of \$10,401,000 and \$15,239,000, respectively, added to the carrying value of the Notes in long-term obligations. In the year ended December 31, 2003 and the period ended December 31, 2002, the Company recognized net gains of \$72,000 and \$3,408,000, respectively, related to the net changes in the fair values of these swaps, as well as changes in the fair value of the Notes recognized during those periods that hedge accounting was applied.

Loan receivable

On November 13, 2002, in connection with a co-promotion agreement between Biovail and Reliant (as described in note 21 Co-Promotion and License Arrangements), Biovail, together with certain of Reliant's existing lenders, established an \$85,000,000 secured credit facility in favour of Reliant. Biovail had committed to fund up to \$40,000,000 of this credit facility. This credit facility was available to Reliant, subject to certain financial and non-financial covenants, for general corporate purposes. This credit facility was secured by a first charge over certain property and assets of Reliant.

Interest was calculated daily on the outstanding advances at U.S. prime plus a margin of 2% and was payable in arrears on the first day of each calendar quarter. Prior to March 31, 2005, Reliant could elect to accrue but not make cash payments of interest. Such accrued interest was added to the principal amount of the outstanding advances.

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 20-F

Reliant was entitled to prepay any or all of the outstanding advances at any time without penalty. Commencing March 31, 2005, Reliant was to begin repayment of the outstanding advances in eight equal quarterly instalments, with the final instalment due on December 31, 2006.

In June 2003, this credit facility was increased from \$85,000,000 to \$115,000,000, and Biovail agreed to increase its total commitment to this credit facility from \$40,000,000 to \$70,000,000. All other material terms and conditions were unchanged.

At December 2003, Biovail had advanced a total of \$70,000,000 to Reliant under this credit facility. Coincident with the termination of the co-promotion agreement between the parties, Reliant elected to prepay all of the outstanding advances, plus accrued interest of \$3,195,000. In December 2003, Reliant paid Biovail \$64,266,000 in cash and, in exchange for the remaining \$8,929,000 owing, Biovail agreed to subscribe to Series D Preferred Units of Reliant (as described in note 7 Long-Term Investments).

11. ACCRUED LIABILITIES

	2003	2002
Product returns	\$ 43,289	\$ 27,414
Product rebates and chargebacks	21,601	15,562
Employee costs	16,796	12,690
Interest	9,209	9,512
Zovirax supply price reduction		10,716
Inventory		7,974
Other	14,306	22,137
	\$ 105,201	\$ 106,005

Product returns

In 2003, the Company determined that, based on the trend in the level of returns and exchanges, its provision for product returns related to certain products should be increased, which resulted in a corresponding reduction in product sales.

12. DEFERRED REVENUE

	2003	2002
Up-front research and development fees	\$ 10,900	\$ 13,000
Up-front licensing fees and other	8,063	10,843
Customer prepayments	1,302	3,588
	20,265	27,431
Less current portion	5,765	9,231
	\$ 14,500	\$ 18,200

13. LONG-TERM OBLIGATIONS

	2003	2002
77/8% Senior Subordinated Notes due April 1, 2010	\$ 400,000	\$ 400,000
Unamortized discount	(2,281)	(2,646)
Fair value adjustment	10,401	15,239
	408,120	412,593
Revolving term credit facility	280,000	110,000
Vasotec® and Vaseretic® obligation	45,376	67,942
Zovirax obligation	42,198	80,656
Wellbutrin® and Zyban® obligation	22,407	69,961
Ativan® and Isordil® obligation	17,806	
Deferred compensation	7,020	6,198
	822,927	747,350
Less current portion	58,816	122,590
	\$ 764,111	\$ 624,760

Interest expense on long-term obligations amounted to \$38,987,000, \$28,564,000 and \$20,195,000 in 2003, 2002 and 2001, respectively. Interest expense in 2003, 2002 and 2001 included the amortization of the discounts on long-term obligations of \$6,562,000, \$5,329,000 and \$10,999,000, respectively.

Senior Subordinated Notes

Pursuant to a supplement to its base shelf prospectus dated March 25, 2002, the Company issued, under an indenture dated March 28, 2002, \$400,000,000 aggregate principal amount of unsecured Notes. Interest on the Notes is payable semi-annually in arrears on April 1 and October 1 of each year. The Notes were issued at a price of 99.27% of their aggregate principal amount for an effective yield, if held to maturity, of 8%. Proceeds from the issue amounted to \$384,280,000, net of discount and financing costs.

At any time on or after April 1, 2006, the Company may redeem all or any of the Notes at the following prices, plus accrued and unpaid interest to the date of redemption, if redeemed during the 12 months beginning April 1 of the years indicated below:

Year	Percentage of principal amount
2006	103.938%
2007	101.969%
2008 and thereafter	100.000%

Before April 1, 2005, the Company may redeem up to 35% of the original principal amount of the Notes, with the net cash proceeds of certain sales of the Company's common shares, at 107.875% of the principal amount plus accrued and unpaid interest to the date of redemption.

At December 31, 2003 and 2002, the aggregate market values of the Notes, based on quoted market prices, were \$408,000,000 and \$402,000,000, respectively.

Revolving term credit facility

On December 27, 2000, the Company entered into a definitive agreement with The Bank of Nova Scotia (the "Bank") for a \$300,000,000 revolving term credit facility. This credit facility was fully underwritten by the Bank in anticipation of syndication by the Bank to other financial institutions (collectively, the "Lenders"). Effective June 22, 2001, this credit facility was increased to \$400,000,000 when the Bank and the Lenders committed to portions of this credit facility, which in aggregate exceeded the original commitment. Effective July 25, 2002, this credit facility was further increased to \$600,000,000. This credit facility is revolving in nature for a term of 364 days and may be extended at the request of the Company and at the sole discretion of the Lenders for additional periods of up to 364 days. Such an extension was requested by the Company and agreed to by the Lenders for the 364-day period ending December 25, 2003. In December 2003, the Lenders agreed to an extension of this credit facility to March 25, 2004. Effective March 25, 2004, the Lenders committed to a renewal of this credit facility at \$400,000,000 for a term of 364 days to March 24, 2005. If

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 20-F

the Lenders elect not to further extend the revolving period of this credit facility, the Company may elect to convert amounts then outstanding to a term facility with a final maturity date one year from the then current revolving period maturity date. At December 31, 2003, Biovail classified this credit facility as a long-term obligation to reflect the renewed maturity terms.

Borrowings under this credit facility are secured by a charge over substantially all of the assets and undertakings, including intellectual property, of the Company. The credit agreement includes certain financial and non-financial covenants. The financial covenants require the Company to meet or exceed certain minimum thresholds for shareholders' equity and interest coverage, and not to exceed a maximum threshold in respect of the ratio of debt to earnings before interest, taxes, depreciation and amortization. Non-financial covenants include, but are not limited to, restrictions on investments and dispositions, as well as capital and debt-restructuring activities, exceeding established thresholds. On a change in control, the Lenders have the right to require the Company to settle this entire credit facility, plus accrued and unpaid interest at the date of settlement.

Borrowings may be by way of U.S. dollar, LIBOR or U.S. base rate advances or Canadian dollar prime rate or bankers' acceptance ("BA") advances or letters of credit. Interest is charged at the Bank's quoted rate plus a borrowing margin of 1.375% to 2% in the case of LIBOR and BA advances, and 0.375% to 1% in the case of base rate and prime rate advances, depending on the Company's financial covenant ratios at the time of such borrowing. The effective rate of interest at both December 31, 2003 and 2002 was 3.74%.

At December 31, 2003 and 2002, respectively, the Company had advances of \$280,000,000 and \$110,000,000 borrowed under this credit facility, and a letter of credit of \$61,207,000 and \$93,170,000 issued under this credit facility. At December 31, 2003 and 2002, respectively, the Company had remaining balances of \$58,793,000 and \$396,830,000 available to borrow under this credit facility. At March 31, 2004, the Company had advances of \$200,000,000 borrowed under this credit facility, and a letter of credit of \$61,207,000 issued under this credit facility, for a remaining balance of \$138,793,000 available to borrow under this credit facility.

Zovirax obligation

The Zovirax obligation relates to the amendments to the Zovirax distribution agreement. This non-interest bearing obligation was discounted based on an imputed interest rate of 3.74%. The remaining payments are payable annually in four gross instalments of \$11,250,000 on March 31 of each year, beginning in 2004.

Wellbutrin® and Zyban® obligation

This obligation relates to the acquisition of the Canadian rights to Wellbutrin® and Zyban®. This non-interest bearing obligation was discounted based on an imputed interest rate of 3.74%. The remaining payment was made on March 1, 2004.

Vasotec® and Vaseretic® obligation

This obligation reflects the minimum fixed royalty payments assumed on the acquisition of Vasotec® and Vaseretic®. This non-interest bearing obligation was discounted based on an imputed interest rate of 5.75%. The remaining payments are payable semi-annually, on April 1 and October 1 of each year, in the following gross annual amounts: 2004 \$19,747,000; 2005 \$15,256,000; and 2006 \$14,011,000.

Ativan® and Isordil® obligation

This obligation reflects the two remaining fixed annual payments related to the acquisition of Ativan® and Isordil®. This non-interest bearing obligation was discounted based on an imputed interest rate of 3.00%. The payments of \$9,150,000 each are due on May 31 of 2004 and 2005.

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 20-F

Maturities

Aggregate maturities of long-term obligations for the years ending December 31 are as follows:

	Notes	Revolving term credit facility	Other	Total
2004	\$	\$	62,669	\$ 62,669
2005		210,000	35,656	245,656
2006		70,000	25,261	95,261
2007			11,250	11,250
2008				
Thereafter	400,000			400,000
Total gross maturities	400,000	280,000	134,836	814,836
Unamortized discounts	(2,281)		(7,049)	(9,330)
Fair value adjustment	10,401			10,401
Deferred compensation ⁽¹⁾			7,020	7,020
Total long-term obligations	\$ 408,120	\$ 280,000	\$ 134,807	\$ 822,927

(1)

The deferred compensation obligation is repayable to the participants in the deferred compensation plan upon their retirement or earlier withdrawal from this plan and, consequently, this obligation does not have a defined maturity.

14. SHAREHOLDERS' EQUITY

Authorized and issued shares

Share offerings

In November 2001, the Company completed a share offering by issuing 12,500,000 common shares for gross proceeds of \$587,500,000 less issue costs of \$27,454,000.

Stock repurchase programs

In November 2003, the Company implemented a stock repurchase program pursuant to which it is able to repurchase up to 10% of its issued and outstanding common shares on or before November 25, 2004. Any common shares purchased by the Company under this program will be cancelled. No common shares have been repurchased under this program.

In February 2002, the Company implemented a stock repurchase program pursuant to which it was able to repurchase up to 5% of its issued and outstanding common shares. In May 2002, the Company increased the amount to 10% of its issued and outstanding common shares. An aggregate of 12,872,300 common shares were repurchased under this program, through open market transactions on the NYSE and TSX, at an average purchase price of \$39.08 per share, for total consideration of \$503,100,000. The excess of the cost of the common shares acquired over the stated capital thereof, totaling \$388,204,000, was charged to deficit. This program was terminated with no further common shares repurchased.

In September 2001, the Company implemented a stock repurchase program pursuant to which it was able to repurchase up to \$120,000,000 of its issued and outstanding common shares. In total, 2,871,200 common shares were repurchased under this program, through open market transactions on the NYSE, at an average purchase price of \$41.79 per share, for total consideration of \$119,987,000. The excess of the cost of the common shares acquired over the stated capital thereof, totaling \$105,633,000, was charged to deficit.

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 20-F

Stock Option Plan

Under the Company's Stock Option Plan, as amended (the "Plan"), the Company may grant to directors, officers, employees, consultants and advisors options to purchase common shares of the Company. The purpose of the Plan is to provide long-term incentives and rewards to the Company's directors, officers, employees, consultants and advisors. The aggregate number of shares reserved for issuance under the Plan, taking into consideration stock splits, shall not exceed 28,000,000 common shares. The number of shares reserved for issuance to any one person under the Plan, together with shares that this person may acquire under any similar plan of the Company, may not exceed 5% of the total issued and outstanding common shares. Under the Plan, the Company designates the maximum number of shares that are subject to an option. The exercise price per share of an option is the closing market price at which the common shares are traded on the NYSE on the day prior to the date the option is granted, or if not so traded, the average between the closing bid and ask prices thereof as reported for that day.

The options' vesting terms vary based on the type of options. Management options granted prior to January 1, 1999, vest as to one-third each year commencing on the first anniversary of the grant and will expire on a date not later than five years from the date of the grant.

Options granted after January 1, 1999, vest as follows: executive options vest pursuant to the terms and conditions of the employment agreement; special options vest on the second anniversary date of the grant; management options vest as to one-fourth each year commencing on March 1 and expire not later than seven years from the date of the grant.

The following table summarizes the Company's stock option activity for the three years ended December 31, 2003:

	Options (000s)	Weighted average exercise price
Outstanding balance, December 31, 2000	10,049	\$ 15.58
Granted	314	43.03
Exercised	(2,906)	9.92
Forfeited	(1,204)	17.69
Outstanding balance, December 31, 2001	6,253	18.53
Granted	2,068	36.84
Exercised	(2,197)	8.71
Forfeited	(199)	28.48
Outstanding balance, December 31, 2002	5,925	28.23
Granted	2,304	27.66
Exercised	(663)	17.50
Forfeited	(234)	31.93
Outstanding balance, December 31, 2003	7,332	\$ 28.91

The weighted average fair values per stock option granted during 2003, 2002 and 2001 were \$11.48, \$13.58 and \$15.34, respectively.

The following table summarizes information about options outstanding at December 31, 2003:

Range of exercise prices	Outstanding (000s)	Weighted average contractual life (years)	Weighted average exercise price	Exercisable (000s)	Weighted average exercise price
(1) \$0.81 \$3.52	65	6.0	\$ 3.06	56	\$ 2.99
8.75 12.77	352	0.8	9.41	352	9.41
17.50 25.00	2,580	3.5	20.90	1,689	22.00
27.72 39.00	2,972	3.9	32.52	1,164	33.22
\$40.00 48.07	1,363	3.3	42.44	678	42.30
	7,332	3.5	\$ 28.91	3,939	\$ 27.41

(1)

These options represent the converted DJ Pharma unvested employee stock options pursuant to the merger agreement.

F-32

Employee Stock Purchase Plan ("EPP")

The Company's EPP was approved by the shareholders at the Special Shareholders' Meeting held on January 1, 1996, and was established in 1996. The purpose of the EPP is to provide a convenient method for full-time employees of the Company to participate in the share ownership of the Company or to increase their share ownership in the Company via payroll or contractual deduction. Directors, senior officers or insiders of the Company are not eligible to participate in the EPP. The aggregate number of shares reserved for issuance under the EPP, taking into consideration stock splits, shall not exceed 1,200,000 common shares. At the discretion of a committee of the Board of Directors that administers the EPP, the Company may issue directly from treasury or purchase shares in the market from time to time to satisfy the obligations under the EPP. A participant may authorize a payroll or contractual deduction up to a maximum of 10% of the base salary or remuneration to be received during any purchase period. The purchase price shall be 90% of the fair market value per share of stock on the date on which the eligible period ends. At December 31, 2003, a total of 64,000 shares have been issued under the EPP.

Executive Stock Purchase Plan ("ESPP") loans

In September 2001, the Company made ESPP loans in an aggregate amount of \$9,988,000 to certain executive officers in order to finance the acquisition of common shares of the Company on the open market. These loans were full recourse and were secured by the common shares purchased pursuant to these loans and bore interest at a rate equal to the Company's rate for borrowings. Interest was payable quarterly in arrears. These loans were due and payable on September 30, 2003.

At December 31, 2003, four executive officers were indebted to the Company in an aggregate amount of \$7,990,000 in connection with the ESPP loans. To facilitate repayment of these loans, on December 31, 2003, Mr. Melnyk, Chairman of the Board and Chief Executive Officer of Biovail, in his individual capacity, made loans to these executives in an amount equal to the amount of their indebtedness to the Company and the ESPP loans from the Company were repaid. These executives pledged to Mr. Melnyk, as collateral for their loans, an aggregate of 176,080 shares of the Company and their interest in 200,000 options to acquire shares of the Company having a strike price of \$31.00 per share. The loan arrangements provide that there will be no recourse to these executives in addition to the collateral pledged by them, except in certain instances.

Warrants outstanding

At September 30, 1999, the Company had 3,737,500 warrants issued and outstanding. Each warrant entitled the holder to purchase four common shares of the Company. The warrants were exercisable at a per share price of \$10.00 from October 1, 1999 until September 30, 2002.

During 2001, the Company issued 27,600 common shares, on the exercise of 6,900 warrants, for proceeds of \$276,000. In addition, the Company entered into privately negotiated agreements with certain holders of its outstanding warrants. These agreements provided for the exercise of 758,300 warrants to purchase 3,033,200 common shares. As an inducement to these holders to exercise, the Company paid these holders approximately \$2.00 per warrant exercised. In aggregate, the Company received proceeds of \$28,817,000 net of the inducement cost of \$1,515,000.

During 2002, substantially all of the remaining outstanding warrants were exercised, resulting in the issue of 11,282,284 common shares, on the exercise of 2,820,571 warrants, for proceeds of \$112,823,000. On September 30, 2002, any remaining warrants expired.

15. WRITE-DOWN OF ASSETS

2003 write-down of assets

In 2003, the Company recorded a charge of \$45,081,000 related to the write-down of the following assets:

In December 2003, the Company evaluated its future interest in its Cedax and Rondec product lines. The Company intends to focus its therapeutically aligned sales efforts on cardiovascular products, such as Cardizem® LA and Teveten®, as well as Zovirax. Without continued promotion the economic viability of Cedax and Rondec would be substantially lower, as these products require significant marketing and sales efforts in order to maintain market share. The Company evaluated the current and forecasted market shares for Cedax and Rondec and determined that the undiscounted future cash flows from these products were below the carrying values of the related product rights. Accordingly, the Company recorded a charge of \$43,400,000 to write down the carrying values of these product rights to their estimated fair values.

In December 2003, the Company recorded a charge of \$1,681,000 related to the write-down of goodwill.

2002 write-down of assets

In 2002, the Company recorded a charge of \$31,944,000 related to the write-down of the following assets:

In June 2002, the Company, Elan Corporation, plc ("Elan") and the U.S. Federal Trade Commission ("FTC") entered into a settlement with respect to the introduction of generic versions of Adalat CC. As a result of the FTC settlement, the agreements between the Company and Elan related to the Company's in-licensing of Elan's generic versions of Adalat CC were dissolved. Consequently, the Company's long-term obligation to make minimum license payments to Elan under these agreements was terminated. The Company had been in negotiations to have Elan reacquire the rights to its generic versions of Adalat CC that had been sold to Biovail. As there had been no meaningful progress to these negotiations as at December 31, 2002, and as Biovail was unable to ascertain the eventual outcome of these negotiations, Biovail determined that the net book value of the generic Adalat CC product rights of \$55,787,000, net of the corresponding long-term obligation to Elan of \$33,381,000, should be written off. In December 2002, the Company recorded a related charge of \$22,406,000. In June 2003, the Company settled with Elan (as described in note 16 Settlements).

During 2002, the Company recorded unrealized holding losses of \$7,398,000 and \$676,000, to reflect other than temporary declines in the values of its investment in Depomed and other investments, respectively, and recorded other asset write-downs of \$1,464,000.

2001 write-down of assets

In 2001, the Company recorded a charge of \$80,482,000 related to the write-down of the following assets:

On March 7, 2001, Eli Lilly and Company ("Lilly") announced a voluntary recall of Keftab tablets due to problems with the product's stability. Lilly was under contract with the Company to manufacture and supply the product to the Company for marketing in the United States. At December 31, 2001, this product's manufacturing problems had yet to be resolved by Lilly. The supply interruption resulted in a deterioration of customer awareness of this product, which would have required substantial promotional efforts to restore if this product were to have been re-launched. Due to these conditions that existed at December 31, 2001, the Company determined that the Keftab product right had been permanently impaired and the net book value should be written down to the estimated recoverable value of \$10,000,000. The Company recorded a related charge of \$54,565,000.

The Company believed Lilly was responsible for manufacturing and supplying acceptable products to Biovail, as well as for the cost of the recall. In this regard, the Company commenced a legal action against Lilly in which Biovail was seeking damages as a result of Lilly's voluntary recall of Keftab. In March 2003, the Company settled with Lilly (as described in note 16 Settlements).

In November 2000, the FDA requested a voluntary recall of products containing phenylpropanolamine ("PPA"). The Company immediately stopped shipments of its Dura-Vent products containing PPA and initiated a recall of these products from wholesalers and pharmacies. During 2001, the Company experienced supply interruptions resulting from manufacturing issues associated with its remaining Dura-Vent products that did not contain PPA. Dura-Vent was manufactured and supplied to the Company by a third party. These supply interruptions caused the Company's revenue and gross margin for the remaining Dura-Vent products to significantly deteriorate. The Company evaluated the current and forecasted market share for these products and determined that the Dura-Vent product right had been permanently impaired and the net book value should be written off. The Company recorded a related charge of \$18,966,000.

During 2001, the Company recorded other asset write-downs, and an unrealized holding loss to reflect an other than temporary decline in the value of an investment, of \$6,951,000.

16. SETTLEMENTS

Pfizer Inc. ("Pfizer"), Bayer AG, Bayer Corporation, Teva Pharmaceuticals USA, Inc. ("Teva"), Mylan Pharmaceuticals Inc. ("Mylan"), Mylan Laboratories Inc.

In June 2003, the Company negotiated an overall settlement with the above captioned entities through which all pending actions relating to generic versions of Procardia XL (Nifedical XL) and Adalat CC, including actions alleging patent infringement and antitrust breaches, were dismissed. The settlement payment comprised the following amounts: (i) a recovery for the profit lost by the Company on sales of Nifedical XL; (ii) compensation for the value of dated Nifedical XL in inventory; (iii) a reduction of legal and other expenses incurred by the Company during the six months ended June 30, 2003; and (iv) interest. In connection with the settlement, the Company was granted a royalty-free, non-exclusive sublicense to U.S. Patent No. 4,264,446.

Elan

In June 2003, the Company settled with Elan with respect to the termination of the Company's rights to Elan's 30 mg and 60 mg generic versions of Adalat CC. In consideration, the parties agreed to settle certain amounts that were owed between them. The net settlement payment from Elan comprised a reimbursement for certain charges related to the supply of these products.

Lilly

In March 2003, the Company negotiated a full and final settlement with Lilly with respect to Lilly's breach of contract due to its inability to supply Keftab to the Company and, as a result, the Company returned all of its right, title and interest in Keftab to Lilly. The settlement payment comprised the following amounts: (i) a recovery of the gross profit lost by the Company on account of Lilly's recall of Keftab and a share of the value of the Keftab product right that was written off by the Company in December 2001; (ii) the recoverable value of the Keftab product right recorded in intangible assets; (iii) compensation for the value of the destroyed Keftab inventory recorded as a long-term receivable from Lilly; (iv) a reimbursement for legal and other expenses incurred by the Company during the three months ended March 31, 2003; and (v) interest.

Mylan

In March 2003, an arbitration tribunal awarded the Company damages with respect to Mylan's breach of contract relating to its failure to supply verapamil (generic Verelan) to the Company. The settlement payment comprised the following amounts: (i) a recovery of the profit lost by the Company on sales of its generic version of Verelan; (ii) a reimbursement for legal expenses incurred by the Company during the three months ended March 31, 2003; and (iii) interest.

During 2003, in relation to the matters described above, the Company recorded settlement payments of \$34,055,000, mainly related to the Company's lost profits on sales of Nifedical XL, Keftab and its generic version of Verelan, and additional payments of \$16,229,000, mainly related to a reduction in cost of goods sold, a reimbursement of legal and other expenses, and interest income. In addition, the Company recorded \$14,554,000 of the settlement payment from Lilly as a reduction to assets related to the recoverable value of the Keftab product right and the value of the destroyed Keftab inventory.

17. DEBT CONVERSION PREMIUMS

Under an indenture dated March 22, 2000, the Company issued \$300,000,000 aggregate principal amount of 6.75% Convertible Subordinated Preferred Equivalent Debentures due March 31, 2025 ("Debentures") for gross proceeds of \$300,000,000. After deducting financing costs of \$11,228,000, the net proceeds from the issue amounted to \$288,772,000. At the holders' option, the Debentures were convertible at any time into common shares of the Company at \$30.337 per common share.

During 2001, the Company entered into privately negotiated agreements with certain holders of the Debentures. These agreements provided for the issuance of 6,278,663 common shares to those certain Debenture holders on their surrender of \$173,845,000 aggregate principal amount of outstanding Debentures. The Company recorded a debt conversion premium of \$23,682,000, which represented the market value of the additional shares issued in excess of the number of shares that would have been issued under the terms of the conversion ratio provided for in the indenture governing the Debentures. The Company also recorded an increase to common shares of \$192,623,000, which included the debt conversion premium, combined with the carrying value of the Debentures on the date of surrender of \$168,941,000. The carrying value of the Debentures comprised the aggregate principal amount of the Debentures plus accrued and unpaid interest to the date of surrender of \$1,250,000, reduced by the proportionate unamortized deferred financing costs related to the Debentures of \$6,154,000.

In October 2001, the Company announced its intention to exercise its option to redeem the remaining \$126,140,000 aggregate principal amount of Debentures on November 27, 2001. Prior to the redemption date, substantially all of the remaining Debentures were converted into 4,154,564 common shares of the Company. The Company recorded a debt conversion premium of \$11,241,000, which represented the aggregate amount of interest that would have been paid on the Debentures from the redemption date to March 31, 2003. The Company also recorded an increase to common shares of \$121,636,000 comprising the aggregate principal amount of the remaining Debentures, reduced by \$108,000 aggregate principal amount of Debentures redeemed for cash on the redemption date, and the proportionate unamortized deferred financing costs related to the Debentures of \$4,396,000.

18. INCOME TAXES

The components of the provision for (or recovery of) income taxes are as follows:

	<u>2003</u>	<u>2002</u>	<u>2001</u>
Current			
Domestic	\$ 400	\$ 1,250	\$ 3,670
Foreign	(4,400)	20,250	10,165
	<u>(4,000)</u>	<u>21,500</u>	<u>13,835</u>
Deferred			
Domestic			
Foreign			1,450
			<u>1,450</u>
	<u>\$ (4,000)</u>	<u>\$ 21,500</u>	<u>\$ 15,285</u>

The reported provision for, or recovery of, income taxes differs from the expected amount calculated by applying the Company's Canadian statutory rate to income or loss before provision for, or recovery of, income taxes. The reasons for this difference and the related tax effects are as follows:

	<u>2003</u>	<u>2002</u>	<u>2001</u>
Income (loss) before provision for (recovery of) income taxes	\$ (31,265)	\$ 109,295	\$ 102,733
Expected Canadian statutory rate	34.10%	39.42%	42.12%
Expected provision for (recovery of) income taxes	<u>(10,661)</u>	<u>43,084</u>	<u>43,271</u>
Non-deductible amounts			
Amortization	45,343	26,130	14,600
Acquired research and development	42,530	66,125	
Foreign tax rate differences	(143,719)	(126,862)	(100,619)
Unrecognized income tax benefit of losses	56,950	9,347	56,760
Other	5,557	3,676	1,273
	<u>\$ (4,000)</u>	<u>\$ 21,500</u>	<u>\$ 15,285</u>

The Company has provided for foreign withholding taxes on the portion of undistributed earnings of foreign subsidiaries expected to be remitted.

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 20-F

Deferred income taxes have been provided for on the following temporary differences:

	<u>2003</u>	<u>2002</u>
Deferred tax assets		
Tax loss carryforwards	\$ 101,132	\$ 68,639
Scientific Research and Experimental Development pool	32,471	17,544
Investment tax credits	23,739	15,948
Provisions	25,576	14,601
Deferred financing and share issue costs	14,125	15,573
Plant, equipment and technology	7,710	4,819
Intangible assets	4,687	
Other	4,079	3,378
	<u>213,519</u>	<u>140,502</u>
Total deferred tax assets	213,519	140,502
Less valuation allowance	(207,932)	(116,521)
	<u>5,587</u>	<u>23,981</u>
Net deferred tax assets	5,587	23,981
Deferred tax liabilities		
Intangible assets		20,958
Other	5,587	3,023
	<u>5,587</u>	<u>23,981</u>
Total deferred tax liabilities	5,587	23,981
Net deferred income taxes	<u>\$</u>	<u>\$</u>

The realization of deferred tax assets is dependent on the Company generating sufficient domestic and foreign taxable income in the years that the temporary differences become deductible. A valuation allowance has been provided for the portion of the deferred tax assets that the Company determined is more likely than not to remain unrealized based on estimated future taxable income and tax planning strategies. During 2003 and 2002, the valuation allowance increased by \$91,411,000 and \$17,836,000, respectively. The increase in the valuation allowance is mainly related to accumulated tax losses and tax credit carryforwards.

At December 31, 2003, the Company had accumulated tax losses of approximately \$8,100,000 available for federal purposes and approximately \$35,800,000 available for provincial purposes in Canada, which expire in 2008 and 2009. The Company also had approximately \$23,300,000 of unclaimed Canadian investment tax credits, which expire from 2004 to 2013. These losses and investment tax credits can be used to offset future years' taxable income and federal tax, respectively.

In addition, the Company has pooled Scientific Research and Experimental Development ("SR&ED") expenditures amounting to approximately \$89,500,000 available to offset against future years' taxable income from its Canadian operations, which may be carried forward indefinitely.

The eventual settlement of the Company's U.S. dollar Notes will likely result in a foreign exchange gain or loss for Canadian income tax purposes. The amount of this gain or loss will depend on the exchange rate between the U.S. and Canadian dollars at the time the Notes are settled. At December 31, 2003, the unrealized foreign exchange gain on the translation of the Notes to Canadian dollars for Canadian income tax purposes was approximately \$92,000,000. If the Notes had been settled at December 31, 2003, one-half of this foreign exchange gain would have been included in the Company's taxable income, which would have resulted in a corresponding reduction in the Company's available Canadian operating losses, SR&ED pool and/or investment tax credit carryforward balances disclosed above.

The Company has accumulated tax losses of approximately \$241,700,000 for federal and state purposes in the United States, which expire from 2007 to 2023. These losses can be used to offset future years' taxable income. There may be limitations on the annual utilization of these losses as a result of certain changes in ownership that have occurred.

19. EARNINGS OR LOSS PER SHARE

Earnings (or loss) per share were calculated as follows:

	2003	2002	2001
	<u> </u>	<u> </u>	<u> </u>
Net income (loss)	\$ (27,265)	\$ 87,795	\$ 87,448
	<u> </u>	<u> </u>	<u> </u>
Basic weighted average number of common shares outstanding (000s)	158,516	151,960	136,928
Dilutive effect of stock options (000s)		2,511	3,579
Dilutive effect of warrants (000s)		5,992	10,183
	<u> </u>	<u> </u>	<u> </u>
Diluted weighted average number of common shares outstanding (000s)	158,516	160,463	150,690
	<u> </u>	<u> </u>	<u> </u>
Basic earnings (loss) per share	\$ (0.17)	\$ 0.58	\$ 0.64
Diluted earnings (loss) per share	\$ (0.17)	\$ 0.55	\$ 0.58
	<u> </u>	<u> </u>	<u> </u>

In 2003, all stock options were excluded from the calculation of diluted loss per share, as the effect of including them would have been anti-dilutive. The potential dilutive effect of stock options on the weighted average number of common shares outstanding was as follows:

	2003
	<u> </u>
Basic weighted average number of common shares outstanding (000s)	158,516
Potential dilutive effect of stock options (000s)	1,403
	<u> </u>
Adjusted weighted average number of common shares outstanding (000s)	159,919
	<u> </u>

In 2001, the Debentures were excluded from the calculation of diluted earnings per share because the effect would have been anti-dilutive.

20. CASH FLOW INFORMATION**Net change in non-cash operating items**

Increases (decreases) in cash flows from operations as a result of changes in non-cash operating items were as follows:

	2003	2002	2001
	<u> </u>	<u> </u>	<u> </u>
Accounts receivable	\$ 15,926	\$ (93,241)	\$ 4,778
Inventories	(30,023)	(14,643)	(14,341)
Deposits and prepaid expenses	3,156	(12,265)	(1,296)
Accounts payable	(3,590)	35,717	1,138
Accrued liabilities	(649)	47,578	24,489
Income taxes payable	(10,958)	17,618	10,649
Deferred revenue	(7,166)	(22,699)	(4,103)
	<u> </u>	<u> </u>	<u> </u>
	\$ (33,304)	\$ (41,935)	\$ 21,314
	<u> </u>	<u> </u>	<u> </u>

Non-cash investing and financing activities

In 2003, non-cash investing and financing activities included the long-term obligation of \$17,497,000 related to the acquisition of Ativan® and Isordil®, and the subscription to \$8,929,000 Series D Preferred Units of Reliant in repayment of a portion of the loan receivable from Reliant. In 2002, non-cash investing and financing activities included long-term obligations of \$99,620,000 and \$69,961,000 related to the acquisitions of Vasotec® and Vaseretic®, and Wellbutrin® and Zyban®, respectively, as well as a long-term obligation of \$80,656,000 related to the amendments to the Zovirax

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 20-F

distribution agreement. In 2001, non-cash investing and financing activities included the issuance of common shares of \$314,259,000 on the surrender and redemption of the Debentures.

F-38

Cash paid during the year

	2003	2002	2001
Interest	\$ 31,187	\$ 14,899	\$ 22,837
Income taxes	7,862	5,063	4,380
Debt conversion premiums			11,241

21. CO-PROMOTION AND LICENSE ARRANGEMENTS**Reliant**

In November 2002, Biovail and Reliant entered into a co-promotion agreement to co-promote Biovail's Zovirax, Teveten®, Teveten® HCT, Rondec, Cedax and Cardizem® LA products. Biovail and Reliant would detail these products to physicians in the United States during the period from October 1, 2002 to December 31, 2005. In addition, Biovail would spend a minimum prescribed amount on advertising and sales promotion of these products. In consideration of Reliant's co-promotion activities under this agreement, Biovail would pay Reliant a tiered co-promotion fee based on a percentage of the quarterly net sales of these products.

Commencing on June 30, 2003, each of Biovail and Reliant had the right to terminate this agreement for any reason. In the event that either party terminated this agreement, Biovail could elect to either pay Reliant a termination fee, as defined in this agreement, or continue to pay Reliant trailing royalties on sales of the co-promoted products through to December 31, 2008. In the event that Biovail elected to continue to pay Reliant these royalties, Reliant could elect to terminate the payment of these royalties on the withdrawal from the market or sale of any of the products, in which case Biovail would pay Reliant the termination fee. This agreement was to expire on December 31, 2008.

Effective April 1, 2003, Biovail and Reliant amended certain terms of this agreement, such that Reliant was responsible for one-half of certain advertising and sales promotion costs incurred during 2003 related to the co-promoted products. Accordingly, Biovail's selling, general and administrative expenses in 2003 were recorded net of a reimbursement of \$25,000,000 received from Reliant. The amended terms also increased the tiered co-promotion fee payable to Reliant.

Effective December 31, 2003, Biovail and Reliant mutually agreed to terminate the co-promotion agreement (as amended). Consequently, Biovail recorded a charge of \$61,348,000 to extinguish its trailing royalty obligation to Reliant.

During the period covered by the co-promotion agreement (as amended), Biovail made loans to Reliant, which were repaid by Reliant coincident with the termination of this agreement (as described in note 10 Other Assets).

GSK

In October 2001, Biovail and GSK entered into an agreement for the development and license of Wellbutrin XL and the co-promotion of Wellbutrin SR®. Under the terms of this agreement, Biovail licensed Wellbutrin XL to GSK for sale and distribution in the United States. Biovail also granted GSK the option to elect to license Wellbutrin XL for sale and distribution on a worldwide basis, excluding Canada. Biovail and GSK collaborated to complete the development of Wellbutrin XL and to obtain FDA approval for this product. In addition, GSK and Biovail co-promoted GSK's Wellbutrin SR® in the United States during the period from January 1, 2002 to March 31, 2003. In consideration for the activities undertaken by Biovail under this agreement, GSK committed to pay Biovail up to \$61,500,000 in six quarterly increments. The first increment of \$11,500,000 was related to the development of Wellbutrin XL. During 2002, Biovail completed the development of Wellbutrin XL and recognized the first increment in research and development revenue. The five remaining quarterly increments, of up to \$10,000,000 each, related to the co-promotion of Wellbutrin SR® in the United States. The receipt of each of these increments was dependent on Biovail performing prescribed detailing activity related to the co-promotion of Wellbutrin SR®, and the amount was determined based on a percentage of net sales of Wellbutrin SR® in the United States during each quarter. Biovail received the full amount of these increments in each of the four quarters of 2002 and the first quarter of 2003.

GSK filed an NDA for Wellbutrin XL with the FDA in August 2002 and received FDA approval for this product in August 2003. GSK has elected to exercise its option to develop and market Wellbutrin XL in the European Union and in certain other key Western, Central and East European markets, as well as in Asia, Latin America, the Middle East, Africa and certain other emerging world markets.

Under the terms of this agreement, Biovail is the exclusive manufacturer and supplier of Wellbutrin XL to GSK on a worldwide basis. The sale prices for trade product shipped to GSK during each calendar year are determined based on a tiered percentage of GSK's net selling prices (after taking into consideration GSK's provisions for estimated discounts, returns, rebates and chargebacks). The sale prices for sample product shipped to GSK are fixed based on the terms of this agreement.

22. RESEARCH AND DEVELOPMENT COLLABORATIONS

In the ordinary course of business, the Company enters into research and development collaborations with third parties to provide formulation and other services for its products under development. These collaborations target the Company's therapeutic areas of focus cardiovascular (including Type II diabetes), pain management and central nervous system, and typically include formulation and product development services being rendered by the developer. The developer may utilize its own technology, and, in other cases, the Company will allow access to its technology for the formulation and development of the product(s). In some cases, the Company has an ownership interest or an option to take an ownership position in the developer. In no case is the Company responsible for any of the developers' third party liabilities, nor has the Company guaranteed any debts, nor is the Company required under any circumstances to exercise any of its options.

These third party developers are typically compensated on the basis of fees for service, milestone payments or royalty payments from the future sales of the products under development, or some combination of these bases. In addition, in the ordinary course of business, the Company may enter into research and development collaborations with third parties whereby the Company may provide contract research, formulation development and other services to those third parties. The Company is typically compensated on the basis of fees for service, milestone payments, royalties from future sales of the product(s) or some combination of these bases.

BNC-PHARMAPASS

In July 2003, Biovail and PPII formed BNC-PHARMAPASS to advance the development of carvedilol, tamsulosin and eprosartan products (as described in note 3 Acquisitions).

Flamel Technologies S.A. ("Flamel")

In February 2003, Biovail licensed from Flamel the rights to manufacture and market an oral solid controlled-release formulation of acyclovir, for the treatment of episodic and recurrent genital herpes infections, in the United States and Canada. Flamel will be responsible for completing the development of this product. Biovail paid Flamel an up-front payment of \$500,000, and Biovail will pay Flamel up to \$6,500,000 on the achievement of certain developmental milestones, as well as royalties on any future sales of this product.

Depomed

In July 2002, Biovail licensed from Depomed the rights to manufacture and market Metformin GR in the United States and Canada. Depomed will be responsible for completing the clinical development program in support of this product. If Metformin GR is approved by the FDA, Biovail will pay Depomed a \$25,000,000 milestone fee, as well as royalties on any future sales of this product.

Merck

In May 2002, Biovail entered into an agreement with Merck to develop, license and supply a new dosage format of a Merck product under development. Utilizing CEFORM technology, Biovail and Merck will conduct the development program and, subject to approval by the FDA, Biovail will manufacture and supply this new dosage format to Merck for commercialization. Biovail is entitled to receive a milestone payment on regulatory approval of \$250,000, as well as royalties on any future sales of this new dosage format.

Ethypharm

In April 2002 (as amended in September 2003 and February 2004), Biovail licensed from Ethypharm the rights to market Tramadol FT and Tramadol/Acetaminophen FT, as well as four other products, in the United States, Canada and Mexico. Biovail will pay Ethypharm a milestone payment of \$1,000,000 if Tramadol FT is approved by the FDA, and a royalty on any future sales of Tramadol/Acetaminophen FT (as described in note 3 Acquisitions). Biovail will also pay up to \$45,000,000 in milestone payments on the first regulatory approval of the four other products within the United States, Canada or Mexico, as well as royalties on any future sales of these products. Biovail has also entered into a cross-license agreement with Ethypharm, whereby the two companies grant to each other non-exclusive licenses to use Biovail's CEFORM technology and Ethypharm's Flashtab technology, respectively, relating to the development of new rapid dissolve pharmaceutical products. Biovail has not made any milestone payments to Ethypharm.

Procyon Biopharma Inc. ("Procyon")

In January 2002 (as amended in January 2004), the Company licensed from Procyon the rights to manufacture and market Fibrostat in the United States. Fibrostat is a topical therapeutic for scar management. The Company will pay aggregate fees of approximately \$7,100,000 to Procyon for the development of Fibrostat, subject to the attainment of certain milestones. If Fibrostat is approved by the

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 20-F

FDA, the Company will pay a licensing fee to Procyon of approximately \$3,900,000, as well as royalties on any future sales of Fibrostat. Biovail has not paid any fees to Procyon.

23. LEGAL PROCEEDINGS

From time to time, the Company becomes involved in various legal and administrative proceedings, which it considers to be in the ordinary course of business. These proceedings include product liability, intellectual property, antitrust, governmental investigations and related private litigation. There are also ordinary course employment related issues and other types of claims in which the Company routinely becomes involved but which individually and collectively are not material.

Intellectual property

RhoxalPharma Inc. ("RhoxalPharma") has filed an Abbreviated New Drug Submission ("ANDS") in Canada, seeking approval of a generic version of Tiazac®. The Company has two patents listed in the Patent Registry and has instituted legal proceedings that will prohibit the issuance of a Notice of Compliance to RhoxalPharma until said proceedings are concluded, or until the expiry of 24 months from the date of the Notice of Allegation, whichever is earlier.

Novopharm Limited ("Novopharm") has filed an ANDS in Canada, seeking approval of a generic version of Wellbutrin® SR 100 mg and 150 mg. The Company has instituted legal proceedings that will prohibit the issuance of a Notice of Compliance to Novopharm until these proceedings are concluded, or until the expiry of 24 months after the date of the Notice of Allegation, whichever is earlier.

Torpharm, Inc. ("Torpharm") has filed an Abbreviated New Drug Application ("ANDA") in the United States, seeking approval for a generic version of Cardizem® CD (120 mg, 180 mg, 240 mg and 300 mg). The Company has instituted legal proceedings pursuant to the Hatch-Waxman Act that preclude the FDA from granting approval to Torpharm until the earliest of 30 months after the filing of the legal suit, a court decision of non-infringement or patent invalidity or a court decision to abbreviate the 30-month stay.

Torpharm has filed an ANDA in the United States, seeking approval for a generic version of Tiazac® (120 mg, 180 mg, 240 mg, 300 mg and 360 mg). The Company has instituted legal proceedings pursuant to the Hatch-Waxman Act that preclude the FDA from granting approval to Torpharm until the earliest of 30 months after the filing of the legal suit, a final court decision of non-infringement or patent invalidity, or a court decision to abbreviate the 30-month stay.

Product liability

Biovail Pharmaceuticals, Inc. ("BPI") has been named in two Complaints alleging personal injuries arising from Plaintiffs' use of Dura-Vent, a product containing PPA and formerly marketed by BPI. The Company believes that these claims are without merit and, in the event these actions proceed further, they will be vigorously defended. These actions have been currently stayed pending the outcome of legal proceedings in a larger class of PPA actions. The Company nevertheless believes that these claims are without merit and, in the event these actions proceed further, they will be vigorously defended.

Antitrust

Several class action Complaints have been filed against the Company in which these Plaintiffs have alleged that Biovail has improperly impeded the approval of a generic form of Tiazac. The Company believes that the complaints are without merit and that the Company's actions were in accordance with its rights as contained in the Hatch-Waxman Amendments and the law. Moreover, the position of the Company is that it is not responsible for Andrx Corporation's ("Andrx") inability to receive timely final marketing approval for its generic Tiazac considering that the Andrx product did not receive FDA approval for a lengthy period following the removal of all legal or regulatory impediments by the Company.

The Company has filed its Motion for Summary Judgment seeking to dismiss the consolidated actions.

Several consumer class action suits have been commenced jointly against the Company, Elan and Teva relating to an agreement between the Company and Elan for the in-licensing of Adalat CC products from Elan. The agreement in question has since been dissolved as a result of a settlement agreement with the FTC. Biovail believes these suits are without merit since the delay in the marketing or out-licensing of the Company's Adalat CC product was due to manufacturing difficulties the Company encountered and not because of any improper activity on its part.

The Company has filed an extensive Motion for the summary dismissal of these actions. The Company believes that these claims are without merit and, in the event these actions proceed further, they will be vigorously defended.

The Company had received an informal enquiry from the FTC with respect to the Company's acquisition and listing of certain patents relating to its Teveten® and Teveten® HCT products. The FTC has confirmed that it is satisfied with the Company's responses and will not be pursuing further action on this matter.

Securities Class Actions

The Company has received notification that a number of Securities Class Action Complaints have been filed naming Biovail and certain officers. The Complaints allege the Defendants violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, and Rule 10b-5 promulgated thereunder. More specifically the Complaints allege that Biovail and certain of its officers and directors made materially false and misleading statements during certain specified periods of time.

The legal process will require an amended and consolidated Complaint to be filed. The Company will, thereupon, consider the appropriateness of filing a Motion for the summary dismissal of this action.

The Company believes that these claims are without merit and, in the event these actions proceed further, they will be vigorously defended.

Defamation and tort

On April 29, 2003, Jerry I. Treppel, a former analyst at Banc of America Securities, commenced an action naming as Defendants the Company and certain officers thereof, and against Michael Sitrick and Sitrick & Company, Inc. (in their capacities as consultants to the Company), in which the Plaintiff has alleged that he was defamed by the Defendants and that the Company's actions resulted in damages to him by way of lost employment and employment opportunities.

The Company has filed an extensive brief requesting the summary dismissal of this action. A decision of the Court in this regard is pending.

The Company believes that these claims are without merit and, in the event this action proceeds further, it will be vigorously defended.

Government investigations

The Company has received notification from the U.S. Attorney, District of Massachusetts, on behalf of the U.S. Office of the Inspector General ("OIG") of Health and Human Services that a preliminary administrative inquiry has been initiated into the Company's clinical experience and marketing programs related to Cardizem® LA. The Company is providing the OIG its full cooperation in this inquiry.

The Company has received notification from the SEC indicating that the SEC is conducting an informal inquiry relating to the Company's financial performance for the fiscal year 2003. The Company is providing to the SEC its full cooperation.

The Company has received requests for information from the Ontario Securities Commission ("OSC") as part of the OSC's continuous disclosure review of public companies. The Company is responding and providing all requested information to the OSC.

In addition, the Company has received notification that the OSC "is conducting a routine enquiry into the trading of Biovail Corporation" securities prior to the issuance of press releases on October 3, 2003, which provided guidance for the third quarter, and October 30, 2003, which reported the financial results for the third quarter. The Company is providing the OSC its full cooperation.

Arbitration

On March 1, 2004, Biovail Laboratories Incorporated ("BLI"), a wholly-owned subsidiary of the Company, began legal proceedings through arbitration against Teva Pharmaceuticals Curacao N.V. ("Teva Curacao").

These proceedings stem from perceived improprieties by Teva Curacao in calculating the net sales from a basket of generic products exclusively licensed to Teva Curacao, from which BLI and Teva Curacao are to calculate their respective financial entitlements. These perceived improprieties were detected through a formal audit conducted by an independent accounting firm.

The Company expects these proceedings to be completed within a year from their commencement.

The outcome of all legal proceedings the Company is involved in, including losses that may result therefrom, cannot be reasonably predicted or foreseen. Accordingly, no provisions for potential losses related to any of these proceedings have been accrued for in these consolidated financial statements.

24. CONTRACTUAL OBLIGATIONS**Operating lease commitments**

The Company leases certain facilities, vehicles and equipment under operating leases. Lease payments were approximately \$7,800,000, \$5,000,000 and \$5,200,000 in 2003, 2002 and 2001, respectively.

Future minimum annual lease commitments under operating leases for the years ending December 31 are approximately as follows:

2004	\$ 6,400
2005	7,100
2006	4,900
2007	3,400
2008	2,800
Thereafter	13,600
	<hr/>
Total minimum lease commitments	\$ 38,200
	<hr/>

Contingent milestone payments

The Company may be required to make the following milestone payments under research and development collaborations with third parties. These payments are primarily contingent on receiving regulatory approval for the products under development and, consequently, do not have defined maturities.

	Third party collaborator	Amount
	<hr/>	<hr/>
Tramadol FT, and four other products	Ethypharm	\$ 46,000
Metformin GR	Depomed	25,000
Athpharma products	Athpharma	24,200
Pharma Pass products	PPII	15,985
Colonic Delivery System products	PPII	10,000
Fibrostat	Procyon	7,100
Acyclovir	Flamel	6,500
		<hr/>
		\$ 134,785
		<hr/>

Purchase obligations

In connection with the acquisition of Ativan® and Isordil® (as described in note 3 Acquisitions), Biovail will pay Wyeth a \$20,000,000 additional rights payment, increasing at 10% per annum, on the approval by the FDA of the first Ativan® line extension product that may be developed by Biovail.

In connection with the manufacture and supply of Vasotec® and Vaseretic®, Biovail is obligated to make semi-annual payments to Merck for minimum product quantities (regardless of the actual product supplied). The remaining payments are payable semi-annually, on April 1 and October 1 of each year, in the following gross annual amounts: 2004 \$4,794,000; 2005 \$3,810,000; and 2006 \$3,589,000.

25. RELATED PARTY TRANSACTIONS

In June 2001, the Company acquired a corporate aircraft from an entity controlled by Mr. Melnyk for cash consideration of \$10,475,000. The exchange amount was established based on comparable market prices for this aircraft at the time of acquisition.

In March 2001, the Company loaned \$600,000 to a former executive officer. This loan is secured by a charge on the former officer's personal residence. This loan does not bear interest until March 1, 2004, and thereafter bears interest at a rate equal to the Company's rate of borrowing. This loan is due on

March 31, 2008.

26. SEGMENTED INFORMATION AND MAJOR CUSTOMERS

The Company operates in one operating segment – the development and commercialization of pharmaceutical products. Management assesses performance and makes resource decisions based on the consolidated results of operations of this operating segment.

F-43

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 20-F

Substantially all of the operations of the Company are directly engaged in or support this operating segment. Other operations are not material and share many of the same economic and operating characteristics as pharmaceutical products and, accordingly, they are included with pharmaceutical products for purposes of segment reporting.

Geographic information

	Revenue ⁽¹⁾			Long-lived assets ⁽²⁾		
	2003	2002	2001	2003	2002	2001
Canada	\$ 124,800	\$ 62,848	\$ 44,705	\$ 114,660	\$ 94,519	\$ 44,139
United States and Puerto Rico	692,853	713,615	528,722	182,495	271,122	231,763
Barbados and other Caribbean		9,533	3,448	1,071,082	1,039,868	475,381
Other countries	6,069	2,029	6,388	28,539	27,340	1,249
	\$ 823,722	\$ 788,025	\$ 583,263	\$ 1,396,776	\$ 1,432,849	\$ 752,532

(1) Revenue is attributed to countries based on the location of the customer.

(2) Consists of property, plant and equipment, goodwill, intangible and other assets, net of depreciation and amortization. Property, plant and equipment are attributed to countries based on their physical location, goodwill is attributed to countries based on the location of the related acquired business, and intangible and other assets are attributed to countries based on ownership rights.

Major customers

The following table identifies external customers accounting for 10% or more of the Company's total revenue:

	Percentage of total revenue		
	2003	2002	2001
Customer A	6%	12%	16%
Customer B	13	23	31
Customer C	17	11	9
Customer D	12	9	7
Customer E	11	6	5

27. COMPARATIVE FIGURES

Prior to 2003, the Company included foreign exchange gains or losses as a component of selling, general and administrative expenses. In 2003, the Company adopted the presentation of foreign exchange gains or losses as an individual line item below operating income. The reclassification of a foreign exchange gain of \$700,000 and a foreign exchange loss of \$1,072,000 in 2002 and 2001, respectively, to conform to the presentation adopted in 2003, did not change net income as previously reported in those years.

Certain other of the prior years' figures have been reclassified to conform to the presentation adopted in 2003.

28. SUBSEQUENT EVENTS

BNC-PHARMAPASS

In January 2004, PPII further reduced its interest in BNC-PHARMAPASS through a withdrawal of cash from BNC-PHARMAPASS. In February 2004, Biovail acquired PPII's remaining interest in BNC-PHARMAPASS for \$5,000,000. Biovail and PPII also agreed to terminate the development of tamsulosin, and the intellectual property related to this product was returned to PPII. The increase in Biovail's share of the fair values of the two remaining products (carvedilol and eprosartan), together with the consideration paid to acquire PPII's remaining interest in BNC-PHARMAPASS, resulted in an additional \$8,640,000 charge to acquired research and development in the three months ended March 31, 2004.

Tramadol/Acetaminophen FT

In February 2004, Biovail acquired Tramadol/Acetaminophen FT from Ethypharm, and the parties agreed to amend certain agreements between them (as described in note 3 Acquisitions).

Revolving term credit facility

In March 2004, Biovail renewed its revolving term credit facility (as described in note 13 Long-Term Obligations).

BIOVAIL CORPORATION

MANAGEMENT REPORT

The Company's management is responsible for preparing the accompanying consolidated financial statements in conformity with Canadian generally accepted accounting principles ("GAAP"). In preparing these consolidated financial statements, management selects appropriate accounting policies and uses its judgment and best estimates to report events and transactions as they occur. Management has determined such amounts on a reasonable basis in order to ensure that the consolidated financial statements are presented fairly, in all material respects.

The consolidated financial statements and information contained in the Management's Discussion and Analysis ("MD&A") necessarily include amounts based on informed judgments and estimates of the expected effects of current events and transactions with appropriate considerations to materiality. In addition, in preparing the financial information management must interpret the requirements described above, make determinations as to the relevancy of information to be included, and make estimates and assumptions that affect reported information. The MD&A also includes information regarding the estimated impact of current transactions and events, sources of liquidity and capital resources, operating trends, risks and uncertainties. Actual results in the future may differ materially from our present assessment of this information because future events and circumstances may not occur as expected.

The Company maintains a system of internal accounting controls designed to provide reasonable assurance, at a reasonable cost, that assets are safeguarded and that transactions are executed and recorded in accordance with the Company's policies for doing business. This system is supported by written policies and procedures for key business activities; the hiring of qualified, competent staff; and by a continuous planning and monitoring program.

Ernst & Young LLP has been engaged by the Company's shareholders to audit the consolidated financial statements. During the course of their audit, Ernst & Young LLP reviewed the Company's system of internal controls to the extent necessary to render their opinion on the consolidated financial statements.

The Board of Directors is responsible for ensuring that management fulfills its responsibility for financial reporting and is ultimately responsible for reviewing and approving the financial statements. The Board carries out the responsibility principally through its Audit Committee. The members of the Audit Committee are outside Directors. The Committee considers, for review by the Board of Directors and approval by the shareholders, the engagement or reappointment of the external auditors. Ernst & Young LLP has full and free access to the Audit Committee.

Management acknowledges its responsibility to provide financial information that is representative of the Company's operations, is consistent and reliable, and is relevant for the informed evaluation of the Company's activities.

/s/ EUGENE N. MELNYK

/s/ BRIAN H. CROMBIE

EUGENE N. MELNYK
Chairman of the Board and
Chief Executive Officer

BRIAN H. CROMBIE
Senior Vice President and
Chief Financial Officer

F-46

BIOVAIL CORPORATION

AUDITORS' REPORT

To the Shareholders of
Biovail Corporation

We have audited the consolidated balance sheets of **Biovail Corporation** as at December 31, 2003 and 2002 and the consolidated statements of income (loss), shareholders' equity and cash flows for each of the years in the three-year period ended December 31, 2003. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with Canadian and United States generally accepted auditing standards. Those standards require that we plan and perform an audit to obtain reasonable assurance whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation.

In our opinion, these consolidated financial statements present fairly, in all material respects, the financial position of the Company as at December 31, 2003 and 2002 and the results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2003 in accordance with Canadian generally accepted accounting principles.

On April 23, 2004, we reported separately to the shareholders of **Biovail Corporation** on the consolidated financial statements for the same periods, prepared in accordance with United States generally accepted accounting principles.

Toronto, Canada,
April 23, 2004

/s/ ERNST & YOUNG LLP
ERNST & YOUNG LLP
Chartered Accountants

F-47

BIOVAIL CORPORATION

CONSOLIDATED BALANCE SHEETS

In accordance with Canadian generally accepted accounting principles
(All dollar amounts expressed in thousands of U.S. dollars)

	As at December 31	
	2003 \$	2002 \$
ASSETS		
Current		
Cash and cash equivalents (note 4)	133,261	56,080
Accounts receivable (note 5)	179,374	190,980
Inventories (note 6)	84,058	53,047
Deposits and prepaid expenses	15,759	21,524
	<u>412,452</u>	<u>321,631</u>
Long-term investments (note 7)	92,756	79,324
Property, plant and equipment, net (note 8)	173,804	136,784
Goodwill, net (note 2)	103,429	104,827
Intangible assets, net (notes 2 and 9)	1,457,226	1,500,397
Other assets, net (note 10)	57,937	94,703
	<u>2,297,604</u>	<u>2,237,666</u>
LIABILITIES		
Current		
Accounts payable	67,932	71,641
Accrued liabilities (note 11)	105,201	106,005
Minority interest (note 3)	679	
Income taxes payable	24,175	35,691
Deferred revenue (note 12)	5,765	9,231
Current portion of long-term obligations (note 13)	58,816	122,590
	<u>262,568</u>	<u>345,158</u>
Deferred revenue (note 12)	14,500	18,200
Long-term obligations (note 13)	753,710	609,521
	<u>1,030,778</u>	<u>972,879</u>
SHAREHOLDERS' EQUITY		
Common shares (note 14)	1,469,627	1,455,548
Stock options outstanding	2,290	4,206
Executive Stock Purchase Plan loans (note 14)		(9,988)
Deficit	(222,931)	(182,586)
Cumulative translation adjustment	17,840	(2,393)
	<u>1,266,826</u>	<u>1,264,787</u>

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 20-F

As at December 31

	2,297,604	2,237,666

Commitments and contingencies (*notes 3, 23 and 24*)

On behalf of the Board:

/s/ EUGENE N. MELNYK

EUGENE N. MELNYK

Chairman of the Board and Chief Executive Officer

/s/ LAURENCE E. PAUL

LAURENCE E. PAUL

Director

The accompanying notes are an integral part of the consolidated financial statements.

F-48

BIOVAIL CORPORATION

CONSOLIDATED STATEMENTS OF INCOME (LOSS)

In accordance with Canadian generally accepted accounting principles
(All dollar amounts expressed in thousands of U.S. dollars, except per share data)

	Years ended December 31		
	2003 \$	2002 \$	2001 \$
REVENUE			
Product sales	632,898	645,986	521,154
Research and development	14,239	28,425	14,596
Co-promotion, royalty and licensing	176,585	113,614	47,513
	<u>823,722</u>	<u>788,025</u>	<u>583,263</u>
EXPENSES			
Cost of goods sold (note 3)	139,456	164,706	125,995
Research and development	86,570	52,150	51,017
Selling, general and administrative	242,771	166,397	110,290
Amortization	240,650	125,849	98,097
Write-down of assets (note 15)	82,189	31,944	80,482
Extinguishment of royalty obligation (note 21)	61,348		
Settlements (note 16)	(34,055)		
	<u>818,929</u>	<u>541,046</u>	<u>465,881</u>
Operating income	4,793	246,979	117,382
Interest income	7,165	3,608	2,742
Interest expense (note 13)	(41,286)	(32,005)	(21,060)
Foreign exchange gain (loss)	(14,007)	700	(1,072)
Other expense	(1,010)		
	<u>(44,345)</u>	<u>219,282</u>	<u>97,992</u>
Income (loss) before provision for (recovery of) income taxes	(44,345)	219,282	97,992
Provision for (recovery of) income taxes (note 17)	(4,000)	11,729	(25,998)
	<u>(40,345)</u>	<u>207,553</u>	<u>123,990</u>
Net income (loss)	(40,345)	207,553	123,990
Interest on Convertible Subordinated Preferred Equivalent Debentures (note 18)			(28,436)
Debt conversion premiums (note 18)			(10,001)
	<u>(40,345)</u>	<u>207,553</u>	<u>85,553</u>
Net income (loss) attributable to common shareholders	(40,345)	207,553	85,553
Earnings (loss) per share (note 19)			
Basic	(0.25)	\$ 1.37	\$ 0.62
Diluted	(0.25)	\$ 1.29	\$ 0.57
	<u>(0.25)</u>	<u>\$ 1.29</u>	<u>\$ 0.57</u>
Weighted average number of common shares outstanding (000s) (note 19)			
Basic	158,516	151,960	136,928
Diluted	158,516	160,463	150,690
	<u>158,516</u>	<u>160,463</u>	<u>150,690</u>

The accompanying notes are an integral part of the consolidated financial statements.

BIOVAIL CORPORATION

CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY

In accordance with Canadian generally accepted accounting principles
(All dollar amounts expressed in thousands of U.S. dollars)

	Common shares								Total \$
	Convertible Subordinated Preferred Equivalent Debentures \$	Shares (000s)	Amount \$	Stock options outstanding \$	Executive Stock Purchase Plan loans \$	Warrants outstanding \$	Retained earnings (deficit) \$	Cumulative translation adjustment \$	
Balance, January 1, 2001	301,297	131,461	484,499	2,810		7,912	43,067	(475)	839,110
Issued on the exercise of stock options (note 14)		2,906	29,507	(683)					28,824
Issued under Employee Stock Purchase Plan (note 14)		6	280						280
Cancelled under stock repurchase program (note 14)		(2,871)	(14,354)				(105,633)		(119,987)
Issued pursuant to equity offering (note 14)		12,500	587,500						587,500
Issue costs (note 14)			(27,454)						(27,454)
Convertible Subordinated Preferred									
Equivalent Debentures (note 18)									
Accretion of principal and interest components	28,436						(28,436)		
Interest paid	(13,612)								(13,612)
Issued on surrender and redemption	(316,013)	10,433	339,695				(34,923)		(11,241)
Redeemed for cash	(108)								(108)
Issued on exercise of warrants (note 14)		3,061	30,784			(1,691)			29,093
Cancellation of non-employee options				(735)					(735)
Compensation cost for employee stock options				1,999					1,999
Executive Stock Purchase Plan loans (note 14)					(9,988)				(9,988)
Net income							123,990		123,990
Foreign currency translation adjustment								(2,254)	(2,254)
Balance, December 31, 2001		157,496	1,430,457	3,391	(9,988)	6,221	(1,935)	(2,729)	1,425,417
Issued on the exercise of stock options (note 14)		2,197	20,480	(1,184)					19,296
Issued under Employee Stock Purchase Plan (note 14)		17	463						463
Cancelled under stock repurchase program (note 14)		(12,872)	(114,896)				(388,204)		(503,100)
Issued on exercise of warrants (note 14)		11,282	119,044			(6,221)			112,823
Compensation cost for employee stock options				1,999					1,999
Net income							207,553		207,553
Foreign currency translation adjustment								336	336

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 20-F

Common shares

Balance, December 31, 2002	158,120	1,455,548	4,206	(9,988)	(182,586)	(2,393)	1,264,787
-----------------------------------	---------	-----------	-------	---------	-----------	---------	-----------

F-50

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 20-F

Issued on the exercise of stock options (note 14)	663	13,597	(2,000)			11,597
Issued under Employee Stock Purchase Plan (note 14)	14	482				482
Compensation cost for employee stock options			84			84
Repayment of Executive Stock Purchase Plan loans			9,988			9,988
Net loss					(40,345)	(40,345)
Foreign currency translation adjustment					20,233	20,233
Balance, December 31, 2003	158,797	1,469,627	2,290		(222,931)	1,266,826

The accompanying notes are an integral part of the consolidated financial statements.

BIOVAIL CORPORATION

CONSOLIDATED STATEMENTS OF CASH FLOWS

In accordance with Canadian generally accepted accounting principles
(All dollar amounts expressed in thousands of U.S. dollars)

	Years ended December 31		
	2003 \$	2002 \$	2001 \$
CASH FLOWS FROM OPERATING ACTIVITIES			
Net income (loss)	(40,345)	207,553	123,990
Add (deduct) items not involving cash			
Depreciation and amortization (notes 3, 8 and 9)	257,072	136,718	108,871
Amortization of deferred financing costs (note 10)	2,975	2,267	1,260
Amortization of discounts on long-term obligations (note 13)	7,427	5,329	10,999
Compensation cost for employee stock options	84	1,999	1,999
Write-down of assets (note 15)	82,189	31,944	80,482
Future income taxes (note 17)		(9,771)	(39,833)
Other	5,881		
	315,283	376,039	287,768
Net change in non-cash operating items (note 20)	(33,304)	(41,935)	21,314
Cash provided by operating activities	281,979	334,104	309,082
CASH FLOWS FROM INVESTING ACTIVITIES			
Acquisitions of intangible assets (note 3)	(242,298)	(375,385)	(27,445)
Additions to property, plant and equipment	(36,923)	(61,382)	(44,436)
Acquisitions of businesses, net of cash acquired (note 3)	(25,741)	(240,581)	
Acquisitions of long-term investments (note 7)	(4,555)	(85,119)	(866)
Advance of loan receivable (note 10)	(40,000)	(30,000)	
Repayment of loan receivable (note 10)	61,071		
Proceeds on disposal of intangible asset (note 16)	10,000		
Proceeds on reduction in intangible assets			15,000
Cash used in investing activities	(278,446)	(792,467)	(57,747)
CASH FLOWS FROM FINANCING ACTIVITIES			
Issuance of common shares, net of issue costs (note 14)	12,079	19,615	589,150
Repayment (advance) of Executive Stock Purchase Plan loans (note 14)	9,988		(9,988)
Repurchase of common shares (note 14)		(503,100)	(119,987)
Proceeds from exercise of warrants (note 14)		112,823	29,093
Advances (repayments) under revolving term credit facility, including financing costs (note 13)	169,800	107,895	(211,300)
Repayments of other long-term obligations (note 13)	(119,344)	(41,980)	(193,366)
Issuance of Senior Subordinated Notes, net of financing costs (note 13)		384,280	
Interest paid on Convertible Subordinated Preferred Equivalent Debentures			(13,612)
Paid on redemption of Convertible Subordinated Preferred Equivalent Debentures (note 18)			(11,349)
Cash provided by financing activities	72,523	79,533	58,641
Effect of exchange rate changes on cash and cash equivalents	1,125	19	(229)

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 20-F

	Years ended December 31		
Net increase (decrease) in cash and cash equivalents	77,181	(378,811)	309,747
Cash and cash equivalents, beginning of year	56,080	434,891	125,144
Cash and cash equivalents, end of year	133,261	56,080	434,891

The accompanying notes are an integral part of the consolidated financial statements.

F-52

BIOVAIL CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

**In accordance with Canadian generally accepted accounting principles
(All tabular dollar amounts expressed in thousands of U.S. dollars, except per share data)**

1. GOVERNING STATUTE AND NATURE OF OPERATIONS

Biovail Corporation ("Biovail" or the "Company") is incorporated under the laws of the Province of Ontario, Canada. The Company is a full-service pharmaceutical company, engaged in the formulation, clinical testing, registration, manufacture, promotion and sale of pharmaceutical products utilizing advanced oral drug delivery technologies. The Company's main therapeutic areas of focus are cardiovascular (including Type II diabetes), central nervous system and pain management. The Company's common shares trade on the New York Stock Exchange ("NYSE") and the Toronto Stock Exchange ("TSX") under the symbol BVF.

2. SIGNIFICANT ACCOUNTING POLICIES

Basis of presentation

The consolidated financial statements have been prepared by the Company in U.S. dollars and in accordance with Canadian generally accepted accounting principles ("GAAP"), applied on a consistent basis (except as described below under goodwill and intangible assets). Consolidated financial statements prepared in U.S. dollars and in accordance with U.S. GAAP are separately made available to all shareholders and filed with necessary regulatory authorities.

Principles of consolidation

The consolidated financial statements include the accounts of the Company and those of all its wholly-owned and majority-owned subsidiaries. All significant intercompany transactions and balances have been eliminated.

Use of estimates

In preparing the Company's consolidated financial statements, management is required to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenue and expenses during the reporting periods. Under certain agreements, management relies on estimates and assumptions made by the Company's third party licensees. On an ongoing basis, management reviews its estimates to ensure that these estimates appropriately reflect changes in the Company's business and new information as it becomes available. Significant estimates made by management include allowances for accounts receivable and inventories, provisions for product returns, recalls, rebates and chargebacks, the useful lives of long-lived assets, the expected future cash flows used in evaluating long-lived assets and investments for impairment, the realizability of future tax assets, and the allocation of the purchase price of acquired assets and businesses. If historical experience and other factors used by management to make these estimates do not reasonably reflect future activity, the Company's financial position and results of operations could be materially impacted.

Fair value of financial instruments

Fair value of a financial instrument is defined as the amount at which the instrument could be exchanged in a current transaction between willing parties. The estimated fair values of cash equivalents, accounts receivable, accounts payable, accrued liabilities and income taxes payable approximate their carrying values due to their short maturity periods. The fair values of long-term investments and long-term obligations are based on quoted market prices, if available, or estimated discounted future cash flows. The fair values of derivative contracts are estimated based on the amount that would have been received or paid to settle these contracts.

Cash and cash equivalents

Cash and cash equivalents include highly liquid investments with original maturities of 90 days or less when purchased.

Accounts receivable

The Company performs ongoing credit evaluations of customers and generally does not require collateral. Allowances are maintained for potential credit losses.

Inventories

Inventories comprise raw materials, work in process and finished goods, which are valued at the lower of cost or market, on a first-in, first-out basis. Cost for work in process and finished goods inventories includes materials, direct labour and an allocation of overheads. Market for raw materials is

replacement cost, and for work in process and finished goods is net realizable value.

F-53

Long-term investments

Long-term investments, where the Company does not have the ability to exercise significant influence, are accounted for using the cost method. Declines in the fair value of these investments below their cost basis that are considered to be other than temporary are recognized in net income or loss.

A long-term investment, where the Company has the ability to exercise significant influence, is accounted for using the equity method. The Company's share of the earnings or losses of this company is recognized in net income or loss.

Property, plant and equipment

Property, plant and equipment are reported at cost, less accumulated depreciation. Cost includes interest costs attributable to major capital projects prior to the related assets becoming available for productive use. Depreciation is calculated using the straight-line method, commencing when the assets become available for productive use, based on the following estimated useful lives:

Buildings	25 years
Machinery and equipment	5-10 years
Other equipment	3-10 years
Leasehold improvements	Term of lease

The Company evaluates property, plant and equipment for impairment whenever events or changes in circumstances indicate that the carrying amounts of these assets may not be recoverable. This evaluation is performed by comparing the carrying amounts of these assets to the related estimated undiscounted future cash flows. If these cash flows are less than the carrying amount of the asset, then the carrying amount of the asset is written down to its fair value.

Goodwill and intangible assets

Goodwill represents the excess of the purchase price of acquired businesses over the fair value of the identifiable net assets acquired. Intangible assets acquired through asset acquisitions or business combinations are initially recognized at fair value based on an allocation of the purchase price.

Effective January 1, 2002, the Company adopted The Canadian Institute of Chartered Accountants' ("CICA") Handbook Section 3062, "Goodwill and Other Intangible Assets". Under CICA Handbook Section 3062, goodwill and other intangible assets deemed to have indefinite lives are no longer amortized, but are subject to annual impairment tests. Intangible assets with finite lives continue to be amortized over their estimated useful lives.

Effective January 1, 2002, the Company identified those intangible assets that did not meet the criteria for recognition apart from goodwill, and assessed the useful lives of its remaining intangible assets. As a result, the Company reclassified the \$5,722,000 net carrying amount of workforce related intangible assets, together with the related future tax liability of \$2,429,000, to goodwill and determined that the useful lives of its remaining intangible assets were appropriate and consistent with those useful lives identified at December 31, 2001. The Company does not have any indefinite-lived intangible assets.

On an annual basis, the Company evaluates its goodwill for impairment by comparing the fair values of its reporting units to their respective carrying values. In 2003, the Company completed the annual evaluation of its goodwill and recorded a write-down of \$1,681,000 related to the impairment of goodwill associated with its Swiss subsidiary, Biovail S.A., due to a decline in royalties earned on the sales of products out-licensed by this subsidiary.

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 20-F

A reconciliation of reported net income or loss attributable to common shareholders and earnings or loss per share, assuming CICA Handbook Section 3062 was applied retroactively, is as follows:

	2003	2002	2001
	\$	\$	\$
Net income (loss) attributable to common shareholders as reported	(40,345)	207,553	85,553
Goodwill amortization			5,816
Workforce amortization, net of tax			612
	—————	—————	—————
Adjusted net income (loss) attributable to common shareholders	(40,345)	207,553	91,981
	—————	—————	—————
Basic earnings (loss) per share			
Net income (loss) attributable to common shareholders as reported	(0.25)	1.37	0.62
Goodwill amortization			0.04
Workforce amortization, net of tax			
	—————	—————	—————
Adjusted net income (loss) attributable to common shareholders	(0.25)	1.37	0.66
	—————	—————	—————
Diluted earnings (loss) per share			
Net income (loss) attributable to common shareholders as reported	(0.25)	1.29	0.57
Goodwill amortization			0.04
Workforce amortization, net of tax			
	—————	—————	—————
Adjusted net income (loss) attributable to common shareholders	(0.25)	1.29	0.61
	—————	—————	—————

Intangible assets are reported at cost, less accumulated amortization. Amortization is generally calculated using the straight-line method based on the following estimated useful lives:

Trademarks	20 years
Product rights	8-20 years
Acquired research and development	5-15 years
Technology	15 years

The Company obtained a participating interest in the gross profit on sales of generic omeprazole (as described in note 3 Acquisitions). This interest is being amortized on a proportionate basis relative to the revenue received from this interest.

The costs of assets that are purchased through asset acquisitions or business combinations for a particular research and development project are capitalized as acquired research and development at the time of acquisition and amortized over their estimated useful lives. The amount allocated to acquired research and development is determined by identifying those specific in-process research and development projects that the Company intends to continue, and for which: (i) technological feasibility had not been established at the date of acquisition; and (ii) there was no alternative future use.

The efforts required to develop the acquired research and development into commercially viable products include the completion of the development stages of these projects, clinical-trial testing, regulatory approval and commercialization. The principal risks relating to these projects include the outcomes of the formulation development, clinical studies and regulatory filings. Since pharmaceutical products cannot be marketed without regulatory approvals, the Company will not receive any benefits unless regulatory approval is obtained. The completion of these projects may require significant amounts of future time and effort, as well as additional development costs, which may be incurred by the Company. Consequently, there is significant technological and regulatory approval risk associated with these projects at the date of acquisition.

The research being undertaken on these projects relates specifically to developing novel formulations of the associated molecules. Consequently, the Company does not foresee any alternative future benefit from the acquired research and development other than specifically related to these projects.

The fair value of acquired research and development is determined using an income approach on a project-by-project basis. The estimated future net cash flows related to these projects include the costs to develop these projects into commercially viable products,

and the projected revenues to be earned on commercialization of these projects when complete. The discount rates used to present value the estimated future net cash flows related to each of these projects are determined based on the relative risk of achieving each of these project's net cash flows. The discount rates reflect the project's stage of completion and other risk factors, which include the nature and complexity of the product, the projected costs to complete, market competition and the estimated life of the product.

The Company evaluates intangible assets for impairment whenever events or changes in circumstances indicate that the carrying amounts of these assets may not be recoverable. This evaluation is performed by comparing the carrying amounts of these assets to the related estimated undiscounted future cash flows. If these cash flows are less than the carrying amount of the asset, then the carrying amount of the asset is written down to its fair value.

Advertising

Advertising costs related to new product launches are expensed on the first showing of the product. The Company did not have any deferred advertising costs at December 31, 2003. Deferred advertising costs of \$8,866,000 were included in deposits and prepaid expenses at December 31, 2002.

Advertising costs expensed in 2003, 2002 and 2001 were \$23,013,000, \$18,795,000 and \$3,957,000, respectively. These costs are included in selling, general and administrative expenses.

Deferred financing costs

Deferred financing costs are reported at cost, less accumulated amortization. Amortization is calculated using the straight-line method over the term of the following related obligations:

Revolving term credit facility	3 years
Senior Subordinated Notes	8 years

Amortization expense related to deferred financing costs is included in interest expense.

Deferred compensation plan

The Company maintains a deferred compensation plan to provide certain employees with the opportunity to supplement their retirement income through the deferral of pre-tax income. The assets of this plan were placed in trust, and have been recorded in other assets with a corresponding liability recorded in long-term obligations. The terms of the trust agreement state that the assets of the trust are available to satisfy the claims of general creditors of the Company in the event of bankruptcy, thereby qualifying this trust as a rabbi trust for income tax purposes. Changes in the value of the assets held by this trust, and a corresponding charge or credit to compensation expense (to reflect the fair value of the amount owed to the participants), are recognized in net income or loss.

Derivative financial instruments

The Company manages its exposure to interest rate risks through the use of derivative financial instruments that are designated as a hedge of an identified portion of a recognized long-term obligation. The Company does not utilize derivative financial instruments for trading or speculative purposes. Net receipts or payments relating to the derivative financial instruments are recorded as an adjustment to interest expense. The Company does not recognize unrealized gains or losses resulting from changes in the marked-to-market values of the derivative financial instruments.

In December 2002 (as amended in June 2003), the CICA issued Accounting Guideline ("AcG") No. 13, "Hedging Relationships". AcG No. 13 establishes the criteria for identification, designation, documentation and effectiveness of hedging relationships, for the purpose of applying hedge accounting. AcG No. 13 does not specify hedge-accounting methods. AcG No. 13 is to be applied to hedging relationships in effect in fiscal years beginning on or after July 1, 2003. The Company will adopt the new guidelines effective January 1, 2004.

Foreign currency translation

The financial statements of the Company's operations having a functional currency other than U.S. dollars are translated into U.S. dollars at the rate of exchange prevailing at the balance sheet date for asset and liability accounts and at the average rate of exchange for the reporting period for revenue and expense accounts. The cumulative foreign currency translation adjustment is

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 20-F

recorded as a component of shareholders' equity. Foreign currency gains and losses related to the translation of the Company's Irish operations are recognized in net income or loss.

Foreign currency exchange gains and losses on transactions occurring in a currency other than an operation's functional currency are recognized in net income or loss.

Revenue recognition

Revenue is deemed to be realizable and earned when persuasive evidence of an arrangement exists, delivery has occurred or services have been rendered, the seller's price to the buyer is fixed or determinable, and collectibility is reasonably assured.

In 2000, the Company implemented the provisions of the U.S. Securities and Exchange Commission's ("SEC") Staff Accounting Bulletin ("SAB") No. 101, "Revenue Recognition in Financial Statements", retroactively to January 1, 1998. These policies are generally accepted under Canadian GAAP. Total revenue in 2003, 2002 and 2001 included \$5,200,000, \$4,800,000 and \$6,300,000, respectively, of amortization of revenue deferred on the implementation of SAB No. 101.

Product sales

Product sales revenue is recognized when title has transferred to the customer, provided that the Company has not retained any significant risks of ownership or future obligations with respect to the product sold. Amounts received from customers as prepayments for products to be shipped in the future are reported as deferred revenue.

Revenue from product sales is recognized net of provisions for estimated sales discounts and allowances, returns, recalls, rebates and chargebacks. In connection with these provisions related to sales of products manufactured by the Company for distribution by third party licensees, the Company relies on estimates and assumptions made by these licensees. Provisions for sales discounts and allowances are estimated based on contractual sales terms with customers and historical payment experience. Provisions for returns and recalls are estimated based on historical return and exchange levels, and third party data with respect to inventory levels in the Company's distribution channels. Provisions for rebates and chargebacks are estimated based on historical experience, contractual sales terms with wholesalers and indirect customers, and relevant statutes with respect to governmental pricing programs.

Research and development

Research and development revenue attributable to the performance of contract services is recognized as the services are performed, in accordance with the terms of the specific development contracts. On long-term research and development collaborations, revenue is recognized on a proportionate basis relative to the total level of effort necessary to meet all regulatory and developmental requirements. Costs and profit margin related to these collaborations that are in excess of amounts billed are recorded in accounts receivable, and amounts billed related to these collaborations that are in excess of costs and profit margin are recorded in deferred revenue. Contingent revenue attributable to the achievement of regulatory or developmental milestones is recognized only on the achievement of the applicable milestone. Non-refundable, up-front fees for access to the Company's proprietary technology in connection with certain research and development collaborations are deferred and recognized as revenue on a systematic basis over the term of the related collaboration.

Co-promotion

Co-promotion revenue is recognized based on the terms of the specific co-promotion contracts, and is generally determined based on a percentage of the net sales of the co-promoted products. Sales and marketing costs related to co-promotion revenue are recorded in selling, general and administrative expenses.

Royalty and licensing

Royalty revenue is recognized based on the terms of the specific licensing contracts, and when the Company has no future obligations pursuant to the royalty fee. Royalty revenue is recognized net of amounts payable to sublicensees where the Company is simply acting as an agent for the sublicensee. Licensing revenue is deferred and recognized on a systematic basis over the license period.

Research and development

Research costs related to internal research and development programs and fees for service and milestone payments paid to third parties are expensed as incurred. Development costs related to internal research and development programs are expensed as incurred unless they meet the criteria for deferral. The Company did not have any deferred development costs at December 31, 2003 or 2002.

Costs associated with revenue generated from research and development collaborations, and with providing contract research services are included in research and development expenses and were \$9,503,000, \$11,570,000 and \$7,596,000 in 2003, 2002 and 2001, respectively.

Co-promotion fees

Co-promotion fees payable by the Company to its co-promotion partner were accrued based on a percentage of the net sales of the co-promoted products. Co-promotion fees were included in selling, general and administrative expenses.

Stock-based compensation

Under the provisions of CICA Handbook Section 3870, "Stock-Based Compensation and Other Stock-Based Payments", companies can either measure the compensation cost of equity instruments issued under employee compensation plans using a fair value-based method or can recognize compensation cost using another method, such as the intrinsic value-based method. However, if another method is applied, pro forma disclosure of net income and earnings per share must be presented in the financial statements as if the fair value-based method had been applied. All stock-based awards granted to non-employees must be accounted for at fair value.

The Company recognizes employee stock-based compensation costs under the intrinsic value-based method. Accordingly, no compensation expense for stock options granted to employees at fair market value was recognized in net income or loss in 2003, 2002 or 2001; however, the Company recorded compensation expense in these years for stock options granted (at the date of acquisition) to the employees of DJ Pharma, Inc. ("DJ Pharma"). The following table presents the Company's pro forma net income or loss attributable to common shareholders and earnings or loss per share as if the fair value-based method of CICA Handbook Section 3870 had been applied for all stock options granted:

	2003	2002	2001
	\$	\$	\$
Net income (loss) attributable to common shareholders as reported	(40,345)	207,553	85,553
Total pro forma stock-based compensation expense determined under fair value-based method	(16,903)	(14,254)	(12,216)
Pro forma net income (loss) attributable to common shareholders	(57,248)	193,299	73,337
Basic earnings (loss) per share			
As reported	(0.25)	1.37	0.62
Pro forma	(0.36)	1.27	0.54
Diluted earnings (loss) per share			
As reported	(0.25)	1.29	0.57
Pro forma	(0.36)	1.20	0.49

The weighted average fair values of all stock options granted during 2003, 2002 and 2001 were \$11.48, \$13.58 and \$15.34, respectively, estimated as of the date of grant using the Black-Scholes option-pricing model with the following weighted average assumptions:

	2003	2002	2001
	\$	\$	\$
Expected option life (years)	4.0	3.8	4.0
Volatility	54.7%	46.8%	36.9%
Risk-free interest rate	3.9%	4.5%	5.2%
Dividend yield	%	%	%

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 20-F

The Black-Scholes option-pricing model used by the Company to calculate option values, as well as other currently accepted option valuation models, were developed to estimate the fair value of freely tradeable, fully transferable options without vesting restrictions, which significantly differ from the Company's stock option awards. These models also require highly subjective assumptions, including future stock price volatility and expected time until exercise, which greatly affect the calculated values.

In November 2003, CICA Handbook Section 3870 was amended to require that all stock-based compensation be measured and expensed using a fair value-based methodology. The Company will adopt the new recommendations effective January 1, 2004.

Income taxes

Income taxes are accounted for under the liability method. Future tax assets and liabilities are recognized for the differences between the financial statement and income tax bases of assets and liabilities, and for operating losses and tax credit carryforwards. A valuation allowance is provided for the portion of future tax assets that is more likely than not to remain unrealized. Future tax assets and liabilities are measured using substantively enacted tax rates and laws expected to apply when these assets are expected to be realized or these liabilities are expected to be settled.

Earnings or loss per share

Basic earnings or loss per share are calculated by dividing net income or loss attributable to common shareholders by the weighted average number of common shares outstanding during the reporting period. Diluted earnings or loss per share are calculated by dividing net income or loss attributable to common shareholders by the weighted average number of common shares outstanding during the reporting period after giving effect to dilutive potential common shares. The dilutive effects of stock options and warrants are determined using the treasury stock method. The dilutive effects of convertible securities are determined using the if-converted method.

3. ACQUISITIONS

2003 acquisitions of intangible assets

During 2003, the Company acquired the following intangible assets. Total consideration related to each of these acquisitions was allocated based on the estimated fair values of the acquired assets on the respective dates of acquisition:

	Tramadol FT products \$	Ativan® and Isordil® \$	Athpharma products \$	Generic omeprazole \$	Other \$	Total \$
Acquired assets						
Acquired research and development	16,000	38,100	44,200			98,300
Trademarks		107,542				107,542
Product rights		16,041		35,500	256	51,797
Technology		2,156				2,156
	<u>16,000</u>	<u>163,839</u>	<u>44,200</u>	<u>35,500</u>	<u>256</u>	<u>259,795</u>
Consideration						
Cash paid	16,000	146,342	44,200	35,500	256	242,298
Long-term obligation		17,497				17,497
	<u>16,000</u>	<u>163,839</u>	<u>44,200</u>	<u>35,500</u>	<u>256</u>	<u>259,795</u>

Tramadol FT products

In April 2002, Biovail acquired a 15% equity interest in Ethypharm S.A. ("Ethypharm") and obtained the rights to market six products under development by Ethypharm (as described in note 7 Long-Term Investments and note 22 Research and Development Collaborations). The products under development included Ethypharm's Flashtab versions of tramadol ("Tramadol FT") and combination of tramadol and acetaminophen ("Tramadol/Acetaminophen FT").

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 20-F

September 2003 agreements

In September 2003, Biovail entered into several agreements with Ethypharm relating to: (i) the acquisition of Ethypharm's remaining interest in Tramadol FT (including all relevant patents) and the elimination of Biovail's obligation to make any future milestone payments (except for a \$1,000,000 milestone payment if Tramadol FT is approved by the U.S. Food and Drug Administration ("FDA")) or royalty payments to Ethypharm related to Tramadol FT; (ii) the grant to Ethypharm of a 15-year license to manufacture and market Biovail's controlled-release formulation of diltiazem hydrochloride ("HCl") ("Diltiazem CR"), which is marketed by Biovail in the United States under the trade name Cardizem® LA, in all the countries of the world excluding Canada and the United States; (iii) the supply to Ethypharm of a quantity of diltiazem beads to enable it to encapsulate Diltiazem CR until the necessary technology transfer to manufacture diltiazem beads had been effected; and (iv) the grant to Ethypharm of a right to market Biovail's once-daily formulation of bupropion HCl in all countries outside of North America not elected by GlaxoSmithKline plc ("GSK") pursuant to the Wellbutrin XL agreement between Biovail and GSK (as described in note 21 Co-Promotion and License Arrangements).

In September 2003, Biovail accounted for these transactions on a net basis, reflecting that these agreements were negotiated and concluded almost simultaneously. Biovail recorded a net addition to acquired research and development of \$3,063,000 related to these agreements, reflecting the following amounts that were contractually agreed to by the parties, as well as the cost of the diltiazem beads supplied to Ethypharm:

	\$
Tramadol FT acquisition	21,000
Diltiazem CR proceeds	(20,000)
Cost of diltiazem beads supplied	2,063
Acquired research and development	3,063

Biovail also agreed, subject to certain conditions, to subscribe for up to \$20,000,000 of convertible and/or exchangeable bonds of Ethypharm. Certain of the conditions precedent to the closing of the bond subscription agreement required third parties, independent of Ethypharm and Biovail, to agree to revisions to their existing agreements with Ethypharm.

Biovail also negotiated with Ethypharm for significant improvements to the shareholder agreement, providing equity protection for an indefinite period of time on Biovail's initial investment in Ethypharm in the event of any private or public financing undertaken by Ethypharm.

February 2004 amendments

In February 2004, Biovail and Ethypharm agreed to amend the September 2003 agreements as follows:

The purchase price for Tramadol FT was reduced from \$21,000,000 to \$16,000,000. Biovail remains obligated to pay Ethypharm a \$1,000,000 milestone payment if Tramadol FT is approved by the FDA. In addition to Tramadol FT, Biovail acquired Ethypharm's remaining interest in Tramadol/Acetaminophen FT (including all relevant patents). Biovail will pay Ethypharm a royalty on any future sales of Tramadol/Acetaminophen FT.

The Diltiazem CR license agreement was terminated (including the supply of diltiazem beads), as was the bond subscription agreement. In addition, the term of the equity protection on Biovail's initial investment in Ethypharm was reduced from an indefinite period of time to 18 months. The grant to Ethypharm of a right to market Wellbutrin XL in all countries outside North America was effectively nullified by GSK's subsequent election to develop and market Wellbutrin XL on a worldwide basis.

The February 2004 amendments confirmed conditions that existed at the date of the consolidated financial statements and, accordingly, Biovail recorded these amendments effective December 31, 2003. The effect of these amendments on the original accounting for the September 2003 transactions was as follows: (i) the proceeds from the sales of the Diltiazem CR license and the diltiazem beads were reversed; (ii) the cost of the diltiazem beads was returned to inventory; and (iii) the addition to acquired research and development was increased from \$3,063,000 to \$16,000,000 to reflect the actual cash paid for Tramadol FT and Tramadol/Acetaminophen FT pursuant to the February 2004 amendments.

Acquired research and development

At the dates of acquisition, Tramadol FT was in a late-stage clinical phase of development and Tramadol/Acetaminophen FT was in a pre-clinical phase of development. At the dates of acquisition, neither of these products had been submitted for approval by the FDA. In March 2004, Biovail filed a New Drug Application ("NDA") with the FDA for Tramadol FT (Ralivia FlashDose®). The acquired research and development is being amortized over its estimated useful life of five years.

Ativan® and Isordil®

In May 2003, Biovail acquired from Wyeth Pharmaceuticals Inc. ("Wyeth") the rights to Ativan® (lorazepam), indicated for the management of anxiety disorders, and Isordil® (isosorbide dinitrate), indicated for the prevention of angina pectoris due to coronary artery disease, in the United States. Biovail also acquired a license to use certain technologies relating to Wyeth's Canadian sublingual version of Ativan® to develop new Ativan® line extension products to be sold in the United States. Wyeth will manufacture and supply Ativan® and Isordil® to Biovail for three years from the date of acquisition. Biovail will make two fixed annual payments of \$9,150,000 each to Wyeth under the manufacturing and supply agreement (regardless of the actual product supplied). Biovail will also pay Wyeth royalties on any future sales of any Ativan® line extension products that may be developed and marketed by Biovail, as well as a \$20,000,000 additional rights payment, increasing at 10% per annum, on the approval by the FDA of the first Ativan® line extension product that may be developed by Biovail.

The purchase price for Ativan® and Isordil® was \$163,839,000 comprising cash consideration, including costs of acquisition, of \$146,342,000, and the two remaining fixed annual payments. The remaining fixed annual payments were present valued using an imputed interest rate of 3.00%, which was comparable to Biovail's available borrowing rate at the date of acquisition. Accordingly, the present value of the remaining fixed annual payments was determined to be \$17,497,000.

The fair values of the acquired assets were determined using an income approach. The discount rates used to present value the estimated future cash flows related to each acquired asset were determined based on the relative risk of achieving each asset's estimated future cash flows and were in the range of 10.5% to 35%.

The trademarks are being amortized over their estimated useful lives of 20 years. The product rights and technology are being amortized over their estimated useful lives of 15 years.

Acquired research and development

At the date of acquisition, the Ativan® line extension products were in pre-clinical phases of development, and none of these products had been submitted for approval by the FDA. The discount rates used to present value the estimated future cash flows related to these products were in the range of 30% to 35%. The costs to complete the development of these products are estimated to be up to \$23,500,000. The acquired research and development is being amortized over its estimated useful life of five years.

Athpharma products

In April 2003, Biovail entered into an agreement with Athpharma Limited ("Athpharma") to acquire four cardiovascular products under development for \$44,200,000, including costs of acquisition. The four products under development are Bisochron (bisoprolol), a beta-1 selective beta-blocker formulation for the treatment of hypertension, Isochron (isosorbide-5-mononitrate), a long-acting nitrate formulation for the treatment of angina, and Hepacol I (pravastatin) and Hepacol II (simvastatin), two liver-selective statin formulations for the treatment of high cholesterol. Athpharma will complete the development of these products. Biovail will pay a portion of the development costs, and may make aggregate payments of \$24,200,000 to Athpharma subject to the attainment of certain milestones. Biovail will also pay Athpharma royalties on any future sales of these products.

Acquired research and development

At the date of acquisition, Bisochron and Isochron were both entering Phase III clinical studies, and Hepacol I and Hepacol II were both in pre-clinical phases of development, and none of these products had been submitted for approval by the FDA. The discount rates used to present value the estimated future cash flows related to these products were in the range of 45% to 70%. The following values were assigned to these products: Bisochron \$21,550,000, Isochron \$13,100,000, Hepacol I \$6,985,000 and Hepacol II \$2,565,000. Biovail's share of the costs to complete the development of these products is estimated to be \$20,000,000. The acquired research and development is being amortized over its estimated useful life of five years.

Generic omeprazole

In May 2003, Biovail paid \$35,500,000 to the previous owners of Pharma Pass LLC (a company acquired by Biovail in December 2002, as described below under 2002 acquisitions of businesses) related to an additional participating interest in the gross profit on sales of generic omeprazole owned by those parties. Amortization of \$34,379,000 related to the cost of this acquired asset was recorded in 2003, as Biovail had received most of the value from this participating interest by December 31, 2003.

2002 acquisitions of intangible assets

During 2002, the Company acquired the following intangible assets. Total consideration related to each of these acquisitions was allocated based on the estimated fair values of the acquired assets on the respective dates of acquisition:

	Wellbutrin® and Zyban® \$	Vasotec® and Vaseretic® \$	Teveten® \$	Zovirax \$	Total \$
Acquired assets					
Prepaid expenses	2,609				2,609
Trademarks	24,349	165,804			190,153
Product rights	45,000	79,500	94,340	173,364	392,204
	<u>71,958</u>	<u>245,304</u>	<u>94,340</u>	<u>173,364</u>	<u>584,966</u>
Consideration					
Cash paid, net of gross profit on acquired assets	1,997	145,684	94,340	133,364	375,385
Long-term obligations	69,961	99,620		40,000	209,581
	<u>71,958</u>	<u>245,304</u>	<u>94,340</u>	<u>173,364</u>	<u>584,966</u>

Wellbutrin® and Zyban®

In December 2002, Biovail acquired from GSK the rights to Wellbutrin® SR and Zyban® in Canada. Biovail also acquired the right to market its once-daily formulation of bupropion HCl in Canada under the trade name Wellbutrin® XL if regulatory approval is received. Wellbutrin® SR is prescribed for the treatment of depression and Zyban® is administered for the treatment of nicotine addiction as an aid to smoking cessation. Both products are formulations of bupropion HCl. Biovail obtained the beneficial rights to Wellbutrin® SR and Zyban® effective December 1, 2002, and obtained full legal rights on March 2, 2004, following the completion of the payments described below.

GSK will continue to manufacture and supply Wellbutrin® SR and Zyban® to Biovail for four years from the date of acquisition. GSK will assist in qualifying a Biovail facility to achieve the transition of the manufacturing process. GSK continued to market Wellbutrin® SR and Zyban® in Canada during the period from December 1, 2002 to December 31, 2003 and, in consideration, Biovail paid GSK a tiered royalty on the net sales of these products during this period. Biovail will also pay GSK a royalty on any future sales of Wellbutrin® XL in Canada for a period of 20 years from the date of commercial launch of this product.

The purchase price for Wellbutrin® and Zyban® comprised cash consideration, including costs of acquisition, of \$3,320,000, less GSK's gross profit on the acquired assets from December 1, 2002 (the effective date of the transaction) to December 26, 2002 (the closing date of the transaction) of \$1,323,000, plus remaining payments of \$72,072,000 payable in four quarterly instalments from June 1, 2003 to March 1, 2004. These payments were present valued using an imputed interest rate of 3.74%, which was comparable to Biovail's available borrowing rate at the date of the transaction. Accordingly, the present value of these payments was determined to be \$69,961,000.

The prepaid expenses were amortized over a one-year period from January 1, 2003. These expenses related to the minimum amount that GSK committed to spend on the marketing of Wellbutrin® SR and Zyban® in Canada during that period. The trademarks and product rights are being amortized over their estimated useful lives of 20 years and 15 years, respectively.

Vasotec® and Vaseretic®

In May 2002, Biovail acquired from Merck & Co., Inc. ("Merck") the rights to Vasotec® (enalapril) and Vaseretic® (enalapril and hydrochlorothiazide combination) in the United States. Vasotec® and Vaseretic® are prescribed for the treatments of hypertension and congestive heart failure. Biovail also acquired the fixed-dose combination NDA of enalapril in combination with diltiazem malate. Merck will continue to manufacture and supply Vasotec® and Vaseretic® to Biovail for five years from the date of acquisition. Biovail will make semi-annual payments to Merck over a five-year term for minimum product quantities and a minimum fixed royalty (regardless of the actual product supplied). Biovail will also pay Merck royalties on any future sales of any life cycle products developed and marketed in the United States.

Biovail also entered into a separate agreement with Merck to develop, license and supply a new dosage format of a Merck product under development (as described in note 22 Research and Development Collaborations).

The purchase price for Vasotec® and Vaseretic® comprised cash consideration, including costs of acquisition, of \$155,634,000, less Merck's gross profit on the acquired assets from April 1, 2002 (the effective date of the transaction) to May 10, 2002 (the closing date of the transaction) of \$9,950,000, plus the minimum fixed royalty payments required to be made by Biovail to Merck of \$109,276,000. These payments were present valued using an imputed interest rate of 5.75%, which was comparable to Biovail's available borrowing rate at the date of the transaction. Accordingly, the present value of these payments was determined to be \$99,620,000.

The trademarks and product rights are being amortized over their estimated useful lives of 20 years and 15 years, respectively.

A letter of credit was issued to Merck to secure the remaining semi-annual payments Biovail is required to make under the Vasotec® and Vaseretic® agreement. The letter of credit was issued under Biovail's revolving term credit facility, and had a balance remaining of \$61,207,000 and \$93,170,000 at December 31, 2003 and 2002, respectively. The fees incurred to issue the letter of credit are amortized to interest expense over the related term of the letter of credit.

Teveten®

In March 2002, Biovail acquired from Solvay Pharmaceuticals Marketing & Licensing AG ("Solvay") the rights to Teveten® (eprosartan mesylate) and Teveten® HCT (eprosartan mesylate and hydrochlorothiazide combination) in the United States. Teveten® is an angiotensin-II receptor blocker for the treatment of hypertension and is indicated for use either alone or in conjunction with other antihypertensive medications.

The purchase price for Teveten® comprised cash consideration of \$94,340,000, including costs of acquisition. The product rights are being amortized over their estimated useful life of 20 years.

Solvay will continue to manufacture and supply Teveten® and Teveten® HCT to Biovail for up to 12 years from the date of acquisition, and will assist in qualifying a Biovail facility to achieve the transition of the manufacturing process. Solvay will continue to manufacture and market Teveten® and Teveten® HCT in areas outside of the United States. Solvay paid Biovail a \$20,000,000 marketing allowance to reimburse Biovail for the agreed upon direct costs related to the re-launch and marketing of Teveten® and Teveten® HCT in the United States. Biovail recorded one-half of the marketing allowance each year in 2003 and 2002 as a reduction of selling, general and administrative expenses. Biovail formed a joint business development committee with Solvay to discuss future clinical and product development options that could enhance the performance or expand the utilization of Teveten®. Solvay has the option to acquire, for worldwide markets excluding the United States, all potential future modifications and innovations developed by Biovail for Teveten®.

Zovirax

Effective January 1, 2002, Biovail acquired from GSK the exclusive distribution rights for Zovirax (acyclovir) Ointment and Zovirax Cream in the United States. Zovirax is a topical anti-viral product. Zovirax Ointment is indicated for the treatment of herpes, and Zovirax Cream is indicated for the treatment of cold sores. GSK will continue to manufacture and supply Zovirax Ointment and Zovirax Cream to Biovail over the term of the distribution agreement.

The purchase price for Zovirax comprised cash consideration of \$133,364,000, including costs of acquisition. The product rights were being amortized over their estimated useful life of 10 years, based on the original term of the distribution agreement.

In the event of the termination of the Wellbutrin XL agreement (as described in note 21 Co-Promotion and License Arrangements) by either Biovail or GSK, Biovail would be required to pay GSK additional payments for the rights to Zovirax of \$22,000,000 per year in calendar years 2004 through 2006, and in calendar years 2007 through 2011, Biovail would be required to pay GSK additional payments based on a percentage of Biovail's gross sales of Zovirax during the immediately preceding calendar year.

Effective October 1, 2002, Biovail amended several terms of the original Zovirax distribution agreement with GSK, including a reduction in the supply price for this product. Biovail has been paying the reduced Zovirax supply price since the effective date; however, the reduction in the supply price was subject to repayment if Wellbutrin XL was not approved by the FDA. Accordingly, Biovail had been deferring the value of the reduction in the supply price in accrued liabilities pending the outcome of the Wellbutrin XL approval. In June 2003, GSK received an approvable letter relating to Wellbutrin XL, which raised only routine matters. As a result, Biovail believed that the likelihood of repaying the reduction in the supply price was low and, accordingly, Biovail reversed the accrued liability for the deferred value of the reduction in the supply price. The recognition of the aggregate deferred value of \$25,456,000, as of the date of the approvable letter, was recorded as a reduction to the cost of Zovirax sold in 2003. In August 2003, GSK received FDA approval for Wellbutrin XL.

In December 2002, Biovail and GSK agreed to a 10-year extension of the Zovirax distribution agreement. In consideration for this extension, Biovail paid GSK \$40,000,000 in March 2003. This amount was added to the value of the unamortized Zovirax product rights and, subsequent to the date of amendment, these product rights are being amortized over their revised estimated remaining useful life of 19 years.

2003 acquisition of business

BNC-PHARMAPASS

Description of acquisition

In July 2003, Biovail and Pharma Pass II, LLC ("PPII") formed BNC-PHARMAPASS, LLC ("BNC-PHARMAPASS") to advance the development of three products. These products were carvedilol (Coreg), a beta-blocker indicated for the treatment of congestive heart failure, tamsulosin (Flomax), indicated for the treatment of benign prostatic hyperplasia, and eprosartan (Teveten®). On the formation of BNC-PHARMAPASS, PPII contributed all of its intellectual property relating to these products, which was fair valued at an amount of \$31,350,000, for a 51% interest in this company, and Biovail contributed cash in the amount of \$30,060,000, for a 49% interest in this company. PPII agreed to complete the formulation work in connection with these products. Biovail agreed to pay the cost of all clinical trials and certain other development costs related to these products. Biovail had an option to acquire PPII's interest in BNC-PHARMAPASS for cash consideration plus a royalty on any future sales of these products.

Subsequent to date of formation, PPII reduced its capital in BNC-PHARMAPASS through the withdrawal of \$25,741,000 of cash from BNC-PHARMAPASS. As a result, PPII's interest in BNC-PHARMAPASS was reduced to 16%, and Biovail's interest in BNC-PHARMAPASS increased to 84% at December 31, 2003.

BNC-PHARMAPASS has been consolidated in these financial statements from the date of formation. At December 31, 2003, Biovail's investment in BNC-PHARMAPASS was recorded in these financial statements as follows:

	\$
Cash	4,319
Minority interest	(679)
Acquired research and development	26,420
	<hr/>
Cash contributed	30,060
	<hr/>

Subsequent to December 31, 2003, PPII further reduced its interest in BNC-PHARMAPASS through a withdrawal of cash from BNC-PHARMAPASS, and Biovail exercised its option to acquire PPII's remaining interest in BNC-PHARMAPASS in February 2004 (as described in note 28 - Subsequent Events).

Acquired research and development

At the dates of acquisition, the carvedilol, tamsulosin and eprosartan products were in pre-formulation and formulation phases of development, and none of these products had been submitted for approval by the FDA. The discount rates used to present value the estimated future cash flows related to these products were in the range of 30% to 45%. The costs to complete the development of these products are estimated to be \$50,000,000. The acquired research and development is being amortized over its estimated useful life of five years.

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 20-F

2002 acquisitions of businesses

During 2002, Biovail completed the acquisitions of Pharmaceutical Technologies Corporation ("Pharma Tech") and Pharma Pass LLC and Pharma Pass S.A. (collectively, "Pharma Pass"). These acquisitions were accounted for under the purchase method of accounting. Total consideration, including costs of acquisition, was allocated based on the estimated fair values of the acquired assets on the respective dates of acquisition as follows:

	Pharma Tech \$	Pharma Pass \$	Total \$
	<u> </u>	<u> </u>	<u> </u>
Acquired assets			
Acquired research and development	60,558	107,187	167,745
Product rights	5,000	63,800	68,800
Technology		7,700	7,700
Current liabilities	(3,664)		(3,664)
	<u> </u>	<u> </u>	<u> </u>
Consideration, net of cash acquired	61,894	178,687	240,581
	<u> </u>	<u> </u>	<u> </u>

Pharma Tech

Background

Pharma Tech was a development-stage company engaged in the application of drug delivery technologies to the formulation and development of a portfolio of products. Pharma Tech contracted directly with third parties, including Biovail, to conduct the contract research and development services. Biovail provided contract research and advisory services consistent with contractual relationships it had with other third parties. On the completion of the development of Biovail's products, Biovail had the right to manufacture and sell the products and Pharma Tech was entitled to royalties from the net sales of each product for a period of 10 years from the date of launch of each product. Biovail had options to acquire Pharma Tech's interest in the products or to acquire Pharma Tech.

Prior to the acquisition, Biovail earned revenue from providing advisory and contract research services to Pharma Tech of \$2,844,000 and \$2,189,000 in 2002 and 2001, respectively. The costs of providing these services to Pharma Tech were \$2,053,000 and \$1,679,000 in 2002 and 2001, respectively, and Biovail was reimbursed amounts at cost of \$2,509,000 and \$1,395,000 in 2002 and 2001, respectively. In 2002, Biovail also recorded \$6,689,000 of up-front fees in research and development revenue. These fees had been received from Pharma Tech in 2001, at which time they were deferred for subsequent amortization to revenue. The deferred revenue was fully amortized at December 31, 2002.

Description of acquisition

On December 17, 2002, Biovail paid \$43,080,000 to Pharma Tech to terminate the development by Pharma Tech of one of the products under development and the associated royalties on future sales of this product if approved by the FDA. At the date of termination, this product had not been submitted for approval by the FDA. Accordingly, the termination payment was capitalized as acquired research and development, and is being amortized over its estimated useful life of five years. Biovail is continuing the development program for this product.

On December 31, 2002, Biovail acquired 100% of the outstanding shares of Pharma Tech for \$22,600,000, including costs of acquisition. Through the acquisition of Pharma Tech, Biovail extinguished any future milestone or royalty obligations that Biovail may have had to Pharma Tech resulting from the approval and successful commercialization of any of the products under development, pursuant to the research and development agreements previously entered into between Biovail and Pharma Tech. Pharma Tech has been included in Biovail's consolidated financial statements from the date of acquisition.

The acquired assets of Pharma Tech were fair valued using an income approach. The discount rates used to present value the estimated future cash flows related to each asset were determined based on the relative risk of achieving each asset's estimated future cash flows and were in the range of 30% to 45%.

Acquired research and development

At the date of acquisition, Pharma Tech was involved in a number of product development projects that were in various stages of completion and had not been submitted for approval by the FDA. Subsequent to the date of acquisition, Biovail discontinued one of these projects but is continuing the development programs for the remaining products.

At the date of acquisition, an additional product development project had received an approvable letter from the FDA; however, significant technical issues required resolution before final approval would be granted. Therefore, the technological feasibility of this project had not been established at the date of acquisition. Biovail is continuing to work to resolve these issues.

The acquired research and development is being amortized over its estimated useful life of five years.

Product rights

At the date of acquisition, Pharma Tech was involved with a product development project that had been submitted for approval by the FDA. This product has received an approvable letter from the FDA, which raised only routine matters. Biovail believes that these matters can be successfully resolved and that final approval will be granted. However, since pharmaceutical products cannot be marketed without regulatory approvals, Biovail will not receive any benefits until regulatory approval is obtained. The product rights are being amortized over their estimated useful life of 15 years.

Pro forma information (unaudited)

The following unaudited pro forma information presents a summary of the consolidated results of operations of Biovail and Pharma Tech as if the acquisition had occurred on January 1, 2001. All transactions between Biovail and Pharma Tech have been eliminated.

	2002 \$	2001 \$
Total revenue	778,492	579,815
Net income attributable to common shareholders	152,829	51,962
Basic earnings per share	1.01	0.38
Diluted earnings per share	0.95	0.34

These unaudited pro forma consolidated results have been prepared for comparative purposes only. They do not purport to be indicative of the results of operations that actually would have resulted had Pharma Tech been included in Biovail's consolidated financial statements from January 1, 2001. In addition, they do not purport to be indicative of future consolidated results of operations of Biovail.

Pharma Pass

Background

Pharma Pass was a developer of advanced oral controlled-release technologies and formulations for pharmaceutical companies, including Biovail, in Europe and the United States. On the completion of the development of Biovail's products, Biovail had the right to manufacture and sell the products and Pharma Pass was entitled to royalties from the net sales of each product for a period of 15 years from the date of launch of each product.

Description of acquisition

On December 6, 2002, Biovail acquired 100% of the outstanding interests of Pharma Pass LLC and 100% of the outstanding shares of Pharma Pass S.A. for \$178,687,000, including costs of acquisition. Through the acquisition of Pharma Pass, Biovail extinguished any future milestone or royalty obligations that Biovail may have had to Pharma Pass resulting from the approval and successful commercialization of any of the products under development, pursuant to the research and development agreements previously entered into between Biovail and Pharma Pass. Pharma Pass has been included in Biovail's consolidated financial statements from the date of acquisition.

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 20-F

The acquired assets of Pharma Pass were fair valued using an income approach. The discount rates used to present value the estimated future cash flows related to each asset were determined based on the relative risk of achieving each asset's estimated future cash flows and were generally in the range of 9% to 45%.

Acquired research and development

At the date of acquisition, Pharma Pass was involved in approximately 20 product development projects for a number of pharmaceutical companies including Biovail. At the date of acquisition, a number of these products had been submitted for approval by the FDA. Subsequent to the date of acquisition, one of these products received FDA approval.

The remaining products were in various stages of completion, and are expected to be submitted for approval by the FDA, and/or other regulatory authorities, over approximately the succeeding three years. Biovail is continuing the development programs for these products.

The acquired research and development is being amortized over its estimated useful life of five years.

Product rights

Biovail obtained interests in certain licensed products including Tricor (fenofibrate) and generic omeprazole. Biovail is entitled to royalties on sales of Tricor and a participating interest in the gross profit on sales of generic omeprazole.

The interest in Tricor is being amortized over its estimated useful life of eight years. The cost of the generic omeprazole acquired asset was fully amortized in 2003, as Biovail had received all of the value of this participating interest by December 31, 2003.

Technology

Biovail obtained the patents related to Pharma Pass's Zero Order Release System ("ZORS"), a drug delivery technology that controls the rate of release of a drug and/or significantly enhances the systemic absorption of a drug molecule. Biovail believes the ZORS technology has application to products currently in formulation and to the future development of controlled-release products.

Biovail also obtained Pharma Pass's oral Colonic Delivery System, a drug delivery technology designed for the targeted release of medication into the lower intestine and upper colon. Biovail also has the option to continue the development of four products utilizing this technology. Biovail will pay up to \$10,000,000 in milestone fees subject to the successful completion of the development of these products. Biovail will obtain ownership of the related patents following the net payment of \$10,000,000 less the sum of the milestone fees paid.

The technology is being amortized over its estimated useful life of 15 years.

Pro forma information (unaudited)

The following unaudited pro forma information presents a summary of the consolidated results of operations of Biovail and Pharma Pass as if the acquisition had occurred on January 1, 2001. All transactions between Biovail and Pharma Pass have been eliminated.

	2002 \$	2001 \$
Total revenue	794,827	587,408
Net income attributable to common shareholders	190,138	64,183
Basic earnings per share	1.25	0.47
Diluted earnings per share	1.18	0.43

These unaudited pro forma consolidated results have been prepared for comparative purposes only. They do not purport to be indicative of the results of operations that actually would have resulted had Pharma Pass been included in Biovail's consolidated financial statements from January 1, 2001. In addition, they do not purport to be indicative of future consolidated results of operations of Biovail.

4. CASH AND CASH EQUIVALENTS

	2003	2002
	\$	\$
Cash and bank certificates of deposit	72,928	39,111
Money market funds and corporate debt securities	54,914	16,969
Canadian and U.S. government securities	5,419	
	133,261	56,080

The Company invests its excess cash in high-quality (investment grade 'AA' or better) money market, and government and corporate debt securities.

5. ACCOUNTS RECEIVABLE

	2003	2002
	\$	\$
Trade	159,656	144,748
Less allowances for doubtful accounts and sales discounts	3,954	3,440
	155,702	141,308
Royalties	16,089	30,104
Other	7,583	19,568
	179,374	190,980

The four largest customer balances accounted for 55% of trade and royalties receivables at December 31, 2003. The four largest customer balances accounted for 53% of trade and royalties receivables at December 31, 2002. The Company believes that there is no unusual exposure associated with the collection of these receivables.

6. INVENTORIES

	2003	2002
	\$	\$
Raw materials	25,937	14,949
Work in process	26,803	11,901
Finished goods	31,318	26,197
	84,058	53,047

7. LONG-TERM INVESTMENTS

	2003	2002
	\$	\$
Ethypharm	67,802	67,802
Depomed, Inc.	9,810	6,277
Reliant Pharmaceuticals, LLC	8,929	
Other	6,215	5,245
	92,756	79,324

Ethypharm

In April 2002, Biovail invested \$67,802,000, including costs of acquisition, to acquire 9,794,118 common shares (15% of the issued and outstanding common shares) of Ethypharm.

In addition, Biovail obtained a three-year option to purchase up to 4,080,882 additional common shares of Ethypharm for \$6.66 per share plus 10% per annum, compounded annually. Biovail has not exercised its option.

In September 2003 (as amended in February 2004), Biovail negotiated with Ethypharm for equity protection on its initial investment in Ethypharm in the event of any private or public financing undertaken by Ethypharm on or before June 9, 2005. Biovail is monitoring its investment in Ethypharm, as Ethypharm will need to achieve certain improvements in operating performance or a write-down of this investment may become necessary.

Depomed, Inc. ("Depomed")

In July 2002, Biovail invested \$13,675,000, including costs of acquisition, to acquire 2,465,878 newly issued common shares (15% of the issued and outstanding common shares) of Depomed.

In addition, Biovail obtained a one-year option to purchase up to 821,959 additional common shares of Depomed for \$5.125 per share. Biovail also obtained a three-year option to purchase additional common shares of Depomed, in an amount sufficient for Biovail to increase its investment up to 20% of Depomed's issued and outstanding common shares (calculated following the exercise of the option), for \$5.00 per share plus 20% per annum, compounded monthly. In July 2003, the one-year option expired unexercised. Biovail has not exercised its remaining three-year option.

In July 2002, Biovail also licensed the rights to manufacture and market Depomed's once-daily metformin HCl product ("Metformin GR") (as described in note 22 Research and Development Collaborations).

In April 2003, in connection with a private placement by Depomed, Biovail acquired an additional 1,626,154 common shares of Depomed for \$3,533,000. Biovail also obtained warrants to acquire 569,154 shares of Depomed, which are exercisable from July 2003 until April 2008 at an exercise price of \$2.16 per share.

At December 31, 2003 and 2002, Biovail's investment represented approximately 12% and 15%, respectively, of the issued and outstanding common shares of Depomed. At December 31, 2003 and 2002, the fair values of this investment, based on quoted market prices, were \$30,562,000 and \$6,277,000, respectively. In 2002, Biovail recorded an unrealized holding loss of \$7,398,000 in net income to reflect an other than temporary decline in the value of this investment (as described in note 15 Write-Down of Assets). In 2003, in connection with an increase in the quoted market value of Depomed's common shares, the value of this investment increased by \$20,752,000. This holding gain will not be recorded in net income or loss until realized.

Reliant Pharmaceuticals, LLC ("Reliant")

In December 2003, in connection with the collection of its loan receivable from Reliant (as described in note 10 Other Assets), Biovail subscribed to \$8,929,000 of Series D Preferred Units of Reliant. These units are convertible on a 1:1 basis into Reliant's common units and are senior to all existing preferred classes of units (Series A, B and C) of Reliant. These units do not entitle the holders to a preferred return (or dividends). In the case of a liquidation of Reliant, these units are entitled to a distribution, before any other distribution or payment is made to any unit ranking junior to these units, of an amount equal to the sum of: (i) \$20.00 per unit; and (ii) interest on such amount at a rate of 8.5% per annum from the date of contribution. These units are redeemable by Reliant at a redemption price equal to the preceding amount. These units have voting rights equal to the number of whole common units into which they are convertible. At December 31, 2003, Biovail's investment in these units represented less than 2% of the issued and outstanding common and preferred units of Reliant.

8. PROPERTY, PLANT AND EQUIPMENT

	2003		2002	
	Cost \$	Accumulated depreciation \$	Cost \$	Accumulated depreciation \$
Land	11,378		10,477	
Buildings	75,186	9,742	59,341	6,959
Machinery and equipment	88,594	26,269	62,736	16,920
Other equipment and leasehold improvements	56,083	21,426	42,401	14,292
	<u>231,241</u>	<u>57,437</u>	<u>174,955</u>	<u>38,171</u>
Less accumulated depreciation	<u>57,437</u>		<u>38,171</u>	
	<u>173,804</u>		<u>136,784</u>	

At December 31, 2003 and 2002, the cost of property, plant and equipment included \$20,606,000 and \$54,365,000, respectively, of assets under construction or awaiting FDA approval and not available for productive use. Interest capitalized amounted to \$1,422,000 and \$513,000 in 2003 and 2002, respectively.

Depreciation expense amounted to \$15,351,000, \$9,794,000 and \$9,386,000 in 2003, 2002 and 2001, respectively.

9. INTANGIBLE ASSETS

	2003		2002	
	Cost \$	Accumulated amortization \$	Cost \$	Accumulated amortization \$
Trademarks	703,698	81,371	596,223	47,794
Product rights	575,880	149,193	596,105	61,156
Acquired research and development	561,077	170,201	513,639	113,120
Technology	21,041	3,705	18,885	2,385
	<u>1,861,696</u>	<u>404,470</u>	<u>1,724,852</u>	<u>224,455</u>
Less accumulated amortization	<u>404,470</u>		<u>224,455</u>	
	<u>1,457,226</u>		<u>1,500,397</u>	

Amortization expense amounted to \$239,112,000, \$126,924,000 and \$93,669,000 in 2003, 2002 and 2001, respectively.

10. OTHER ASSETS

	2003 \$	2002 \$
Deferred financing costs	17,311	17,348
Less accumulated amortization	6,274	3,536
	<u>11,037</u>	<u>13,812</u>
Zovirax distribution agreement	40,656	40,656

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 20-F

	<u>2003</u> \$	<u>2002</u> \$
Deferred compensation trust fund	5,644	5,681
Loan receivable		30,000
Long-term receivable		4,554
Other	600	
	<u>57,937</u>	<u>94,703</u>

F-70

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 20-F

Amortization expense related to deferred financing costs amounted to \$2,975,000, \$2,267,000 and \$1,260,000 in 2003, 2002 and 2001, respectively.

Zovirax distribution agreement

In consideration for certain amendments to the original Zovirax distribution agreement with GSK, Biovail agreed to pay GSK \$11,250,000 per year in four annual instalments on March 31 of each year beginning in 2004. The annual instalment payments were present valued using an imputed interest rate of 3.74%, which was comparable to Biovail's available borrowing rate at the date of the transaction. Accordingly, the present value of these payments was determined to be \$40,656,000, which was recorded in other assets. This amount will be amortized over the period of benefit from the amended terms.

Loan receivable

On November 13, 2002, in connection with a co-promotion agreement between Biovail and Reliant (as described in note 21 Co-Promotion and License Arrangements), Biovail, together with certain of Reliant's existing lenders, established an \$85,000,000 secured credit facility in favour of Reliant. Biovail had committed to fund up to \$40,000,000 of this credit facility. This credit facility was available to Reliant, subject to certain financial and non-financial covenants, for general corporate purposes. This credit facility was secured by a first charge over certain property and assets of Reliant.

Interest was calculated daily on the outstanding advances at U.S. prime plus a margin of 2% and was payable in arrears on the first day of each calendar quarter. Prior to March 31, 2005, Reliant could elect to accrue but not make cash payments of interest. Such accrued interest was added to the principal amount of the outstanding advances.

Reliant was entitled to prepay any or all of the outstanding advances at any time without penalty. Commencing March 31, 2005, Reliant was to begin repayment of the outstanding advances in eight equal quarterly instalments, with the final instalment due on December 31, 2006.

In June 2003, this credit facility was increased from \$85,000,000 to \$115,000,000, and Biovail agreed to increase its total commitment to this credit facility from \$40,000,000 to \$70,000,000. All other material terms and conditions were unchanged.

At December 2003, Biovail had advanced a total of \$70,000,000 to Reliant under this credit facility. Coincident with the termination of the co-promotion agreement between the parties, Reliant elected to prepay all of the outstanding advances, plus accrued interest of \$3,195,000. In December 2003, Reliant paid Biovail \$64,266,000 in cash and, in exchange for the remaining \$8,929,000 owing, Biovail agreed to subscribe to Series D Preferred Units of Reliant (as described in note 7 Long-Term Investments).

11. ACCRUED LIABILITIES

	2003	2002
	\$	\$
	_____	_____
Product returns	43,289	27,414
Product rebates and chargebacks	21,601	15,562
Employee costs	16,796	12,690
Interest	9,209	9,512
Zovirax supply price reduction		10,716
Inventory		7,974
Other	14,306	22,137
	_____	_____
	105,201	106,005
	_____	_____

Product returns

In 2003, the Company determined that, based on the trend in the level of returns and exchanges, its provision for product returns related to certain products should be increased, which resulted in a corresponding reduction in product sales.

12. DEFERRED REVENUE

	2003 \$	2002 \$
Up-front research and development fees	10,900	13,000
Up-front licensing fees and other	8,063	10,843
Customer prepayments	1,302	3,588
	<u>20,265</u>	<u>27,431</u>
Less current portion	5,765	9,231
	<u>14,500</u>	<u>18,200</u>

13. LONG-TERM OBLIGATIONS

	2003 \$	2002 \$
7 ⁷ / ₈ % Senior Subordinated Notes due April 1, 2010	400,000	400,000
Unamortized discount	(2,281)	(2,646)
	<u>397,719</u>	<u>397,354</u>
Revolving term credit facility	280,000	110,000
Vasotec® and Vaseretic® obligation	45,376	67,942
Zovirax obligation	42,198	80,656
Wellbutrin® and Zyban® obligation	22,407	69,961
Ativan® and Isordil® obligation	17,806	
Deferred compensation	7,020	6,198
	<u>812,526</u>	<u>732,111</u>
Less current portion	58,816	122,590
	<u>753,710</u>	<u>609,521</u>

Interest expense on long-term obligations amounted to \$38,987,000, \$28,564,000 and \$20,195,000 in 2003, 2002 and 2001, respectively. Interest expense in 2003, 2002 and 2001 included the amortization of the discounts on long-term obligations of \$7,427,000, \$5,329,000 and \$10,999,000, respectively.

Senior Subordinated Notes

Pursuant to a supplement to its base shelf prospectus dated March 25, 2002, the Company issued, under an indenture dated March 28, 2002, \$400,000,000 aggregate principal amount of unsecured 7⁷/₈% Senior Subordinated Notes due April 1, 2010 ("Notes"). Interest on the Notes is payable semi-annually in arrears on April 1 and October 1 of each year. The Notes were issued at a price of 99.27% of their aggregate principal amount for an effective yield, if held to maturity, of 8%. Proceeds from the issue amounted to \$384,280,000, net of discount and financing costs.

At any time on or after April 1, 2006, the Company may redeem all or any of the Notes at the following prices, plus accrued and unpaid interest to the date of redemption, if redeemed during the 12 months beginning April 1 of the years indicated below:

	Percentage of Principal amount
2006	103.938%
2007	101.969%
2008 and thereafter	100.000%

Before April 1, 2005, the Company may redeem up to 35% of the original principal amount of the Notes, with the net cash proceeds of certain sales of the Company's common shares, at 107.875% of the principal amount plus accrued and unpaid interest to the date of redemption.

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 20-F

At December 31, 2003 and 2002, the aggregate market values of the Notes, based on quoted market prices, were \$408,000,000 and \$402,000,000, respectively.

The fair value of the Company's fixed rate Notes is affected by changes in interest rates. The Company manages this exposure to interest rate changes through the use of interest rate swaps. In June 2002, the Company entered into three interest rate swaps of aggregate \$200,000,000 notional amount, which were designated as a hedge of the Notes. These swaps involve the receipt of amounts based on a fixed rate of 7⁷/₈% in exchange for floating rate interest payments, based on six-month London Interbank Offering Rate ("LIBOR") plus a spread of 2.69% to 2.99%, without an exchange of the underlying principal amount. Net receipts or payments relating to these swaps are recorded as an adjustment to interest expense. The unrecognized marked-to-market values of these swaps at December 31, 2003 and 2002 were \$14,746,000 and \$18,647,000, respectively.

Revolving term credit facility

On December 27, 2000, the Company entered into a definitive agreement with The Bank of Nova Scotia (the "Bank") for a \$300,000,000 revolving term credit facility. This credit facility was fully underwritten by the Bank in anticipation of syndication by the Bank to other financial institutions (collectively, the "Lenders"). Effective June 22, 2001, this credit facility was increased to \$400,000,000 when the Bank and the Lenders committed to portions of this credit facility, which in aggregate exceeded the original commitment. Effective July 25, 2002, this credit facility was further increased to \$600,000,000. This credit facility is revolving in nature for a term of 364 days and may be extended at the request of the Company and at the sole discretion of the Lenders for additional periods of up to 364 days. Such an extension was requested by the Company and agreed to by the Lenders for the 364-day period ending December 25, 2003. In December 2003, the Lenders agreed to an extension of this credit facility to March 25, 2004. Effective March 25, 2004, the Lenders committed to a renewal of this credit facility at \$400,000,000 for a term of 364 days to March 24, 2005. If the Lenders elect not to further extend the revolving period of this credit facility, the Company may elect to convert amounts then outstanding to a term facility with a final maturity date one year from the then current revolving period maturity date. At December 31, 2003, Biovail classified this credit facility as a long-term obligation to reflect the renewed maturity terms.

Borrowings under this credit facility are secured by a charge over substantially all of the assets and undertakings, including intellectual property, of the Company. The credit agreement includes certain financial and non-financial covenants. The financial covenants require the Company to meet or exceed certain minimum thresholds for shareholders' equity and interest coverage, and not to exceed a maximum threshold in respect of the ratio of debt to earnings before interest, taxes, depreciation and amortization. Non-financial covenants include, but are not limited to, restrictions on investments and dispositions, as well as capital and debt-restructuring activities, exceeding established thresholds. On a change in control, the Lenders have the right to require the Company to settle this entire credit facility, plus accrued and unpaid interest at the date of settlement.

Borrowings may be by way of U.S. dollar, LIBOR or U.S. base rate advances or Canadian dollar prime rate or bankers' acceptance ("BA") advances or letters of credit. Interest is charged at the Bank's quoted rate plus a borrowing margin of 1.375% to 2% in the case of LIBOR and BA advances, and 0.375% to 1% in the case of base rate and prime rate advances, depending on the Company's financial covenant ratios at the time of such borrowing. The effective rate of interest at both December 31, 2003 and 2002 was 3.74%.

At December 31, 2003 and 2002, respectively, the Company had advances of \$280,000,000 and \$110,000,000 borrowed under this credit facility, and a letter of credit of \$61,207,000 and \$93,170,000 issued under this credit facility. At December 31, 2003 and 2002, respectively, the Company had remaining balances of \$58,793,000 and \$396,830,000 available to borrow under this credit facility. At March 31, 2004, the Company had advances of \$200,000,000 borrowed under this credit facility, and a letter of credit of \$61,207,000 issued under this credit facility, for a remaining balance of \$138,793,000 available to borrow under this credit facility.

Zovirax obligation

The Zovirax obligation relates to the amendments to the Zovirax distribution agreement. This non-interest bearing obligation was discounted based on an imputed interest rate of 3.74%. The remaining payments are payable annually in four gross instalments of \$11,250,000 on March 31 of each year, beginning in 2004.

Wellbutrin® and Zyban® obligation

This obligation relates to the acquisition of the Canadian rights to Wellbutrin® and Zyban®. This non-interest bearing obligation was discounted based on an imputed interest rate of 3.74%. The remaining payment was made on March 1, 2004.

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 20-F

Vasotec® and Vaseretic® obligation

This obligation reflects the minimum fixed royalty payments assumed on the acquisition of Vasotec® and Vaseretic®. This non-interest bearing obligation was discounted based on an imputed interest rate of 5.75%. The remaining payments are payable semi-annually, on April 1 and October 1 of each year, in the following gross annual amounts: 2004 \$19,747,000; 2005 \$15,256,000; and 2006 \$14,011,000.

Ativan® and Isordil® obligation

This obligation reflects the two remaining fixed annual payments related to the acquisition of Ativan® and Isordil®. This non-interest bearing obligation was discounted based on an imputed interest rate of 3.00%. The payments of \$9,150,000 each are due on May 31 of 2004 and 2005.

Maturities

Aggregate maturities of long-term obligations for the years ending December 31 are as follows:

	Notes \$	Revolving term credit facility \$	Other \$	Total \$
2004			62,669	62,669
2005		210,000	35,656	245,656
2006		70,000	25,261	95,261
2007			11,250	11,250
2008				
Thereafter	400,000			400,000
Total gross maturities	400,000	280,000	134,836	814,836
Unamortized discounts	(2,281)		(7,049)	(9,330)
Deferred compensation ⁽¹⁾			7,020	7,020
Total long-term obligations	397,719	280,000	134,807	812,526

(1)

The deferred compensation obligation is repayable to the participants in the deferred compensation plan upon their retirement or earlier withdrawal from this plan and, consequently, this obligation does not have a defined maturity.

14. SHAREHOLDERS' EQUITY

Authorized and issued shares

The authorized capital of the Company comprises an unlimited number of common shares without par value. The Company had 158,796,978 and 158,120,144 issued and outstanding common shares at December 31, 2003 and 2002, respectively.

Share offerings

In November 2001, the Company completed a share offering by issuing 12,500,000 common shares for gross proceeds of \$587,500,000 less issue costs of \$27,454,000.

Stock repurchase programs

In November 2003, the Company implemented a stock repurchase program pursuant to which it is able to repurchase up to 10% of its issued and outstanding common shares on or before November 25, 2004. Any common shares purchased by the Company under this program will be cancelled. No common shares have been repurchased under this program.

In February 2002, the Company implemented a stock repurchase program pursuant to which it was able to repurchase up to 5% of its issued and outstanding common shares. In May 2002, the Company increased the amount to 10% of its issued and outstanding common shares. An aggregate of 12,872,300 common shares were repurchased under this program, through open market transactions on the

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 20-F

NYSE and TSX, at an average purchase price of \$39.08 per share, for total consideration of \$503,100,000. The excess of the cost of the common shares acquired over the stated capital thereof, totaling \$388,204,000, was charged to deficit. This program was terminated with no further common shares repurchased.

In September 2001, the Company implemented a stock repurchase program pursuant to which it was able to repurchase up to \$120,000,000 of its issued and outstanding common shares. In total, 2,871,200 common shares were repurchased under this program, through open market transactions on the NYSE, at an average purchase price of \$41.79 per share, for total consideration of \$119,987,000. The excess of the cost of the common shares acquired over the stated capital thereof, totaling \$105,633,000, was charged to retained earnings.

Stock Option Plan

Under the Company's Stock Option Plan, as amended (the "Plan"), the Company may grant to directors, officers, employees, consultants and advisors options to purchase common shares of the Company. The purpose of the Plan is to provide long-term incentives and rewards to the Company's directors, officers, employees, consultants and advisors. The aggregate number of shares reserved for issuance under the Plan, taking into consideration stock splits, shall not exceed 28,000,000 common shares. The number of shares reserved for issuance to any one person under the Plan, together with shares that this person may acquire under any similar plan of the Company, may not exceed 5% of the total issued and outstanding common shares. Under the Plan, the Company designates the maximum number of shares that are subject to an option. The exercise price per share of an option is the closing market price at which the common shares are traded on the NYSE on the day prior to the date the option is granted, or if not so traded, the average between the closing bid and ask prices thereof as reported for that day.

The options' vesting terms vary based on the type of options. Management options granted prior to January 1, 1999, vest as to one-third each year commencing on the first anniversary of the grant and will expire on a date not later than five years from the date of the grant.

Options granted after January 1, 1999, vest as follows: executive options vest pursuant to the terms and conditions of the employment agreement; special options vest on the second anniversary date of the grant; management options vest as to one-fourth each year commencing on March 1 and expire not later than seven years from the date of the grant.

The following table summarizes the Company's stock option activity for the three years ended December 31, 2003:

	Options (000s)	Weighted average exercise price \$
Outstanding balance, December 31, 2000	10,049	15.58
Granted	314	43.03
Exercised	(2,906)	9.92
Forfeited	(1,204)	17.69
Outstanding balance, December 31, 2001	6,253	18.53
Granted	2,068	36.84
Exercised	(2,197)	8.71
Forfeited	(199)	28.48
Outstanding balance, December 31, 2002	5,925	28.23
Granted	2,304	27.66
Exercised	(663)	17.50
Forfeited	(234)	31.93
Outstanding balance, December 31, 2003	7,332	28.91

The weighted average fair values per stock option granted during 2003, 2002 and 2001 were \$11.48, \$13.58 and \$15.34, respectively.

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 20-F

The following table summarizes information about options outstanding at December 31, 2003:

Range of exercise prices \$	Outstanding (000s)	Weighted average remaining contractual life (years)	Weighted average exercise price \$	Exercisable (000s)	Weighted average exercise price \$
0.81 - 3.52 ⁽¹⁾	65	6.0	3.06	56	2.99
8.75 - 12.77	352	0.8	9.41	352	9.41
17.50 - 25.00	2,580	3.5	20.90	1,689	22.00
27.72 - 39.00	2,972	3.9	32.52	1,164	33.22
40.00 - 48.07	1,363	3.3	42.44	678	42.30
	7,332	3.5	28.91	3,939	27.41

(1)

These options represent the converted DJ Pharma unvested employee stock options pursuant to the merger agreement.

Employee Stock Purchase Plan ("EPP")

The Company's EPP was approved by the shareholders at the Special Shareholders' Meeting held on January 1, 1996, and was established in 1996. The purpose of the EPP is to provide a convenient method for full-time employees of the Company to participate in the share ownership of the Company or to increase their share ownership in the Company via payroll or contractual deduction. Directors, senior officers or insiders of the Company are not eligible to participate in the EPP. The aggregate number of shares reserved for issuance under the EPP, taking into consideration stock splits, shall not exceed 1,200,000 common shares. At the discretion of a committee of the Board of Directors that administers the EPP, the Company may issue directly from treasury or purchase shares in the market from time to time to satisfy the obligations under the EPP. A participant may authorize a payroll or contractual deduction up to a maximum of 10% of the base salary or remuneration to be received during any purchase period. The purchase price shall be 90% of the fair market value per share of stock on the date on which the eligible period ends. At December 31, 2003, a total of 64,000 shares have been issued under the EPP.

Executive Stock Purchase Plan ("ESPP") loans

In September 2001, the Company made ESPP loans in an aggregate amount of \$9,988,000 to certain executive officers in order to finance the acquisition of common shares of the Company on the open market. These loans were full recourse and were secured by the common shares purchased pursuant to these loans and bore interest at a rate equal to the Company's rate for borrowings. Interest was payable quarterly in arrears. These loans were due and payable on September 30, 2003.

At December 31, 2003, four executive officers were indebted to the Company in an aggregate amount of \$7,990,000 in connection with the ESPP loans. To facilitate repayment of these loans, on December 31, 2003, Mr. Melnyk, Chairman of the Board and Chief Executive Officer of Biovail, in his individual capacity, made loans to these executives in an amount equal to the amount of their indebtedness to the Company and the ESPP loans from the Company were repaid. These executives pledged to Mr. Melnyk, as collateral for their loans, an aggregate of 176,080 shares of the Company and their interest in 200,000 options to acquire shares of the Company having a strike price of \$31.00 per share. The loan arrangements provide that there will be no recourse to these executives in addition to the collateral pledged by them, except in certain instances.

Warrants outstanding

At September 30, 1999, the Company had 3,737,500 warrants issued and outstanding. Each warrant entitled the holder to purchase four common shares of the Company. The warrants were exercisable at a per share price of \$10.00 from October 1, 1999 until September 30, 2002.

During 2001, the Company issued 27,600 common shares, on the exercise of 6,900 warrants, for proceeds of \$276,000. In addition, the Company entered into privately negotiated agreements with certain holders of its outstanding warrants. These agreements provided for the exercise of 758,300 warrants to purchase 3,033,200 common shares. As an inducement to these holders to exercise, the Company paid these holders approximately \$2.00 per warrant exercised. In aggregate, the Company received proceeds of \$28,817,000 net of the inducement cost of \$1,515,000.

During 2002, substantially all of the remaining outstanding warrants were exercised, resulting in the issue of 11,282,284 common shares, on the exercise of 2,820,571 warrants, for proceeds of \$112,823,000. On September 30, 2002, any remaining warrants expired.

15. WRITE-DOWN OF ASSETS

2003 write-down of assets

In 2003, the Company recorded a charge of \$82,189,000 related to the write-down of the following assets:

In December 2003, the Company evaluated its future interest in its Cedax and Rondec product lines. The Company intends to focus its therapeutically aligned sales efforts on cardiovascular products, such as Cardizem® LA and Teveten®, as well as Zovirax. Without continued promotion the economic viability of Cedax and Rondec would be substantially lower, as these products require significant marketing and sales efforts in order to maintain market share. The Company evaluated the current and forecasted market shares for Cedax and Rondec and determined that the undiscounted future cash flows from these products were below the carrying values of the related product rights. Accordingly, the Company recorded a charge of \$43,400,000 to write down the carrying values of these product rights to their estimated fair values.

In December 2003, the Company recorded an aggregate charge of \$37,108,000 related to the write-down of acquired research and development associated with product development projects that have been discontinued by the Company.

In December 2003, the Company recorded a charge of \$1,681,000 related to the write-downs of goodwill.

2002 write-down of assets

In 2002, the Company recorded a charge of \$31,944,000 related to the write-down of the following assets:

In June 2002, the Company, Elan Corporation, plc ("Elan") and the U.S. Federal Trade Commission ("FTC") entered into a settlement with respect to the introduction of generic versions of Adalat CC. As a result of the FTC settlement, the agreements between the Company and Elan related to the Company's in-licensing of Elan's generic versions of Adalat CC were dissolved. Consequently, the Company's long-term obligation to make minimum license payments to Elan under these agreements was terminated. The Company had been in negotiations to have Elan reacquire the rights to its generic versions of Adalat CC that had been sold to Biovail. As there had been no meaningful progress to these negotiations as at December 31, 2002, and as Biovail was unable to ascertain the eventual outcome of these negotiations, Biovail determined that the net book value of the generic Adalat CC product rights of \$55,787,000, net of the corresponding long-term obligation to Elan of \$33,381,000, should be written off. In December 2002, the Company recorded a related charge of \$22,406,000. In June 2003, the Company settled with Elan (as described in note 16 Settlements).

During 2002, the Company recorded unrealized holding losses of \$7,398,000 and \$676,000, to reflect other than temporary declines in the values of its investment in Depomed and other investments, respectively, and recorded other asset write-downs of \$1,464,000.

2001 write-down of assets

In 2001, the Company recorded a charge of \$80,482,000 related to the write-down of the following assets:

On March 7, 2001, Eli Lilly and Company ("Lilly") announced a voluntary recall of Keftab tablets due to problems with the product's stability. Lilly was under contract with the Company to manufacture and supply the product to the Company for marketing in the United States. At December 31, 2001, this product's manufacturing problems had yet to be resolved by Lilly. The supply interruption resulted in a deterioration of customer awareness of this product, which would have required substantial promotional efforts to restore if this product were to have been re-launched. Due to these conditions that existed at December 31, 2001, the Company determined that the Keftab product right had been permanently impaired and the net book value should be written down to the estimated recoverable value of \$10,000,000. The Company recorded a related charge of \$54,565,000.

The Company believed Lilly was responsible for manufacturing and supplying acceptable products to Biovail, as well as for the cost of the recall. In this regard, the Company commenced a legal action against Lilly in which Biovail was seeking damages as a result of Lilly's voluntary recall of Keftab. In March 2003, the Company settled with Lilly (as described in note 16 Settlements).

In November 2000, the FDA requested a voluntary recall of products containing phenylpropanolamine ("PPA"). The Company immediately stopped shipments of its Dura-Vent products containing PPA and initiated a recall of these products from wholesalers and pharmacies. During 2001, the Company experienced supply interruptions resulting from manufacturing issues associated with its remaining Dura-Vent products that did not contain PPA. Dura-Vent was manufactured and supplied to the Company by a third party.

These supply interruptions caused the Company's revenue and gross margin for the remaining Dura-Vent products to significantly deteriorate. The Company evaluated the current and forecasted market share for these products and determined that the Dura-Vent product right had been permanently impaired and the net book value should be written off. The Company recorded a related charge of \$18,966,000.

During 2001, the Company recorded other asset write-downs, and an unrealized holding loss to reflect an other than temporary decline in the value of an investment, of \$6,951,000.

16. SETTLEMENTS

Pfizer Inc. ("Pfizer"), Bayer AG, Bayer Corporation, Teva Pharmaceuticals USA, Inc. ("Teva"), Mylan Pharmaceuticals Inc. ("Mylan"), Mylan Laboratories Inc.

In June 2003, the Company negotiated an overall settlement with the above captioned entities through which all pending actions relating to generic versions of Procardia XL (Nifedical XL) and Adalat CC, including actions alleging patent infringement and antitrust breaches, were dismissed. The settlement payment comprised the following amounts: (i) a recovery for the profit lost by the Company on sales of Nifedical XL; (ii) compensation for the value of dated Nifedical XL in inventory; (iii) a reduction of legal and other expenses incurred by the Company during the six months ended June 30, 2003; and (iv) interest. In connection with the settlement, the Company was granted a royalty-free, non-exclusive sublicense to U.S. Patent No. 4,264,446.

Elan

In June 2003, the Company settled with Elan with respect to the termination of the Company's rights to Elan's 30 mg and 60 mg generic versions of Adalat CC. In consideration, the parties agreed to settle certain amounts that were owed between them. The net settlement payment from Elan comprised a reimbursement for certain charges related to the supply of these products.

Lilly

In March 2003, the Company negotiated a full and final settlement with Lilly with respect to Lilly's breach of contract due to its inability to supply Keftab to the Company and, as a result, the Company returned all of its right, title and interest in Keftab to Lilly. The settlement payment comprised the following amounts: (i) a recovery of the gross profit lost by the Company on account of Lilly's recall of Keftab and a share of the value of the Keftab product right that was written off by the Company in December 2001; (ii) the recoverable value of the Keftab product right recorded in intangible assets; (iii) compensation for the value of the destroyed Keftab inventory recorded as a long-term receivable from Lilly; (iv) a reimbursement for legal and other expenses incurred by the Company during the three months ended March 31, 2003; and (v) interest.

Mylan

In March 2003, an arbitration tribunal awarded the Company damages with respect to Mylan's breach of contract relating to its failure to supply verapamil (generic Verelan) to the Company. The settlement payment comprised the following amounts: (i) a recovery of the profit lost by the Company on sales of its generic version of Verelan; (ii) a reimbursement for legal expenses incurred by the Company during the three months ended March 31, 2003; and (iii) interest.

During 2003, in relation to the matters described above, the Company recorded settlement payments of \$34,055,000, mainly related to the Company's lost profits on sales of Nifedical XL, Keftab and its generic version of Verelan, and additional payments of \$16,229,000, mainly related to a reduction in cost of goods sold, a reimbursement of legal and other expenses, and interest income. In addition, the Company recorded \$14,554,000 of the settlement payment from Lilly as a reduction to assets related to the recoverable value of the Keftab product right and the value of the destroyed Keftab inventory.

17. INCOME TAXES

The components of the provision for (or recovery of) income taxes are as follows:

	2003 \$	2002 \$	2001 \$
Current			
Domestic	400	1,250	3,670
Foreign	(4,400)	20,250	10,165
	<u>(4,000)</u>	<u>21,500</u>	<u>13,835</u>
Future			
Domestic			
Foreign		(9,771)	(39,833)
		<u>(9,771)</u>	<u>(39,833)</u>
	<u>(4,000)</u>	<u>11,729</u>	<u>(25,998)</u>

The reported provision for, or recovery of, income taxes differs from the expected amount calculated by applying the Company's Canadian statutory rate to income or loss before provision for, or recovery of, income taxes. The reasons for this difference and the related tax effects are as follows:

	2003 \$	2002 \$	2001 \$
Income (loss) before provision for (recovery of) income taxes	(44,345)	219,282	97,992
Expected Canadian statutory rate	34.10%	39.42%	42.12%
Expected provision for (recovery of) income taxes	<u>(15,122)</u>	<u>86,441</u>	<u>41,274</u>
Non-deductible amount			
Amortization	79,360	43,942	33,309
Foreign tax rate differences	(131,065)	(133,068)	(102,386)
Unrecognized income tax benefit of losses	57,270	10,738	
Other	5,557	3,676	1,805
	<u>(4,000)</u>	<u>11,729</u>	<u>(25,998)</u>

The Company has provided for foreign withholding taxes on the portion of undistributed earnings of foreign subsidiaries expected to be remitted.

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 20-F

Future income taxes have been provided for on the following temporary differences:

	2003	2002
	\$	\$
	_____	_____
Future tax assets		
Tax loss carryforwards	101,132	68,639
Scientific Research and Experimental Development pool	32,471	17,544
Investment tax credits	23,739	15,948
Provisions	25,576	14,601
Deferred financing and share issue costs	14,125	15,573
Plant, equipment and technology	7,710	4,819
Intangible assets	4,687	
Other	4,079	3,378
	_____	_____
Total future tax assets	213,519	140,502
Less valuation allowance	(170,816)	(75,255)
	_____	_____
Net future tax assets	42,703	65,247
	_____	_____
Future tax liabilities		
Intangible assets	39,974	63,250
Other	2,729	1,997
	_____	_____
Total future tax liabilities	42,703	65,247
	_____	_____
Net future income taxes	_____	_____

The realization of future tax assets is dependent on the Company generating sufficient domestic and foreign taxable income in the years that the temporary differences become deductible. A valuation allowance has been provided for the portion of the future tax assets that the Company determined is more likely than not to remain unrealized based on estimated future taxable income and tax planning strategies. During 2003 and 2002, the valuation allowance increased by \$95,561,000 and \$15,256,000, respectively. The increase in the valuation allowance is mainly related to accumulated tax losses and tax credit carryforwards.

At December 31, 2003, the Company had accumulated tax losses of approximately \$8,100,000 available for federal purposes and approximately \$35,800,000 available for provincial purposes in Canada, as well as approximately \$23,300,000 of unclaimed Canadian investment tax credits. These losses and investment tax credits can be used to offset future years' taxable income and federal tax, respectively.

The Company has accumulated tax losses of approximately \$241,700,000 for federal and state purposes in the United States, which can be used to offset future years' taxable income. There may be limitations on the annual utilization of these losses as a result of certain changes in ownership that have occurred.

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 20-F

These tax losses and investment tax credits expire as follows:

	Tax losses			
	Canada			
	Federal \$	Provincial \$	United States \$	Investment tax credits \$
2004				600
2005				1,300
2006				1,400
2007			4,300	1,700
2008	3,400	23,400	6,100	3,700
2009	4,700	12,400	6,700	500
2010			3,100	3,200
2011			16,400	2,900
2012			15,500	4,300
2013				3,700
2018			22,100	
2019			13,500	
2020			1,100	
2021			38,500	
2022			15,900	
2023			98,500	
	8,100	35,800	241,700	23,300

In addition, the Company has pooled Scientific Research and Experimental Development ("SR&ED") expenditures amounting to approximately \$89,500,000 available to offset against future years' taxable income from its Canadian operations, which may be carried forward indefinitely.

The eventual settlement of the Company's U.S. dollar Notes will likely result in a foreign exchange gain or loss for Canadian income tax purposes. The amount of this gain or loss will depend on the exchange rate between the U.S. and Canadian dollars at the time the Notes are settled. At December 31, 2003, the unrealized foreign exchange gain on the translation of the Notes to Canadian dollars for Canadian income tax purposes was approximately \$92,000,000. If the Notes had been settled at December 31, 2003, one-half of this foreign exchange gain would have been included in the Company's taxable income, which would have resulted in a corresponding reduction in the Company's available Canadian operating losses, SR&ED pool and/or investment tax credit carryforward balances disclosed above.

18. DEBT CONVERSION PREMIUMS

Under an indenture dated March 22, 2000, the Company issued \$300,000,000 aggregate principal amount of 6.75% Convertible Subordinated Preferred Equivalent Debentures due March 31, 2025 ("Debentures"). After deducting financing costs of \$11,228,000, the net proceeds from the issue amounted to \$288,772,000. At the holders' option, the Debentures were convertible at any time into common shares of the Company at \$30.337 per common share. The value of the Debentures was comprised of the holder conversion option and the interest and principal components. The value ascribed to the option component was determined using the residual method after calculating the amount attributable to the interest and principal components, which were discounted at a rate of interest that would have approximated the rate applicable to non-convertible debt at the time the Debentures were issued. The present value of the interest and principal components amounted to \$256,494,000, resulting in a value of \$43,506,000 being ascribed to the holder conversion option. The present value of the interest and principal components was being accreted to the face value of the payments over the three-year period preceding the first redemption date on March 31, 2003, and was included in the determination of net income attributable to common shareholders. The value of the principal component was net of financing costs.

During 2001, the Company entered into privately negotiated agreements with certain holders of the Debentures. These agreements provided for the issuance of 6,278,663 common shares to those certain Debenture holders upon their surrender of \$173,845,000 aggregate face value of outstanding Debentures. The Company recorded the market value of the additional shares issued in excess of the number of shares that would have been issued under the terms of the conversion ratio provided for in the indenture as follows:

(i) the portion related to the interest and principal components of the Debentures as a \$6,200,000 deduction from net income for the determination of net income attributable to common shareholders; and (ii) the portion related to the holder conversion option as a \$17,482,000 charge to retained earnings. The Company recorded an increase to common shares of \$206,076,000, which included the deduction from net income and the charge to retained earnings combined with the carrying value of the Debentures on the date of surrender of \$182,394,000. The carrying value of the Debentures comprised the holder conversion option and the interest and principal components of the Debentures of \$187,651,000 and the unpaid accrued interest to the date of surrender of \$1,250,000, reduced by the proportionate financing costs of \$6,507,000.

In October 2001, the Company announced its intention to exercise its option to redeem the remaining \$126,140,000 aggregate face value of Debentures on November 27, 2001. Prior to the redemption date, substantially all of the remaining Debentures were converted into 4,154,564 common shares of the Company. The Company recorded the aggregate amount of interest that would have been paid on the Debentures from the redemption date to March 31, 2003 of \$11,241,000 as follows: (i) the portion related to the interest and principal components of the Debentures as a \$3,801,000 deduction from net income for the determination of net income attributable to common shareholders; and (ii) the portion related to the holder conversion option as a \$7,440,000 charge to retained earnings. The Company recorded an increase to common shares of \$133,619,000, which represented the carrying value of the Debentures converted prior to the redemption date. The carrying value of the Debentures comprised the holder conversion option and the interest and principal components of the Debentures of \$138,340,000, reduced by the proportionate financing costs of \$4,721,000. Debentures of \$108,000 aggregate face value were redeemed for cash on the redemption date.

In 2001, interest on the Debentures comprised interest of \$14,862,000 and the accretion of the principal and interest components of \$13,574,000.

19. EARNINGS OR LOSS PER SHARE

Earnings (or loss) per share were calculated as follows:

	2003	2002	2001
Net income (loss) attributable to common shareholders	\$ (40,345)	\$ 207,553	\$ 85,553
Basic weighted average number of common shares outstanding (000s)	158,516	151,960	136,928
Dilutive effect of stock options (000s)		2,511	3,579
Dilutive effect of warrants (000s)		5,992	10,183
Diluted weighted average number of common shares outstanding (000s)	158,516	160,463	150,690
Basic earnings (loss) per share	\$ (0.25)	\$ 1.37	\$ 0.62
Diluted earnings (loss) per share	\$ (0.25)	\$ 1.29	\$ 0.57

In 2003, all stock options were excluded from the calculation of diluted loss per share, as the effect of including them would have been anti-dilutive. The potential dilutive effect of stock options on the weighted average number of common shares outstanding was as follows:

	2003
Basic weighted average number of common shares outstanding (000s)	158,516
Potential dilutive effect of stock options (000s)	1,403
Adjusted weighted average number of common shares outstanding (000s)	159,919

In 2001, the Debentures were excluded from the calculation of diluted earnings per share because the effect would have been anti-dilutive.

20. CASH FLOW INFORMATION**Net change in non-cash operating items**

Increases (decreases) in cash flows from operations as a result of changes in non-cash operating items were as follows:

	2003 \$	2002 \$	2001 \$
Accounts receivable	15,926	(93,241)	4,778
Inventories	(30,023)	(14,643)	(14,341)
Deposits and prepaid expenses	3,156	(12,265)	(1,296)
Accounts payable	(3,590)	35,717	1,138
Accrued liabilities	(649)	47,578	24,489
Income taxes payable	(10,958)	17,618	10,649
Deferred revenue	(7,166)	(22,699)	(4,103)
	<u>(33,304)</u>	<u>(41,935)</u>	<u>21,314</u>

Non-cash investing and financing activities

In 2003, non-cash investing and financing activities included the long-term obligation of \$17,497,000 related to the acquisition of Ativan® and Isordil®, and the subscription to \$8,929,000 Series D Preferred Units of Reliant in repayment of a portion of the loan receivable from Reliant. In 2002, non-cash investing and financing activities included long-term obligations of \$99,620,000 and \$69,961,000 related to the acquisitions of Vasotec® and Vaseretic®, and Wellbutrin® and Zyban®, respectively, as well as a long-term obligation of \$80,656,000 related to the amendments to the Zovirax distribution agreement. In 2001, non-cash investing and financing activities included the issuance of common shares of \$316,013,000 on the surrender and redemption of the Debentures.

Cash paid during the year

	2003 \$	2002 \$	2001 \$
Interest	31,187	14,899	22,837
Income taxes	7,862	5,063	4,380
Debt conversion premiums			11,241
	<u>39,049</u>	<u>19,962</u>	<u>38,458</u>

21. CO-PROMOTION AND LICENSE ARRANGEMENTS**Reliant**

In November 2002, Biovail and Reliant entered into a co-promotion agreement to co-promote Biovail's Zovirax, Teveten®, Teveten® HCT, Rondec, Cedax and Cardizem® LA products. Biovail and Reliant would detail these products to physicians in the United States during the period from October 1, 2002 to December 31, 2005. In addition, Biovail would spend a minimum prescribed amount on advertising and sales promotion of these products. In consideration of Reliant's co-promotion activities under this agreement, Biovail would pay Reliant a tiered co-promotion fee based on a percentage of the quarterly net sales of these products.

Commencing on June 30, 2003, each of Biovail and Reliant had the right to terminate this agreement for any reason. In the event that either party terminated this agreement, Biovail could elect to either pay Reliant a termination fee, as defined in this agreement, or continue to pay Reliant trailing royalties on sales of the co-promoted products through to December 31, 2008. In the event that Biovail elected to continue to pay Reliant these royalties, Reliant could elect to terminate the payment of these royalties on the withdrawal from the market or sale of any of the products, in which case Biovail would pay Reliant the termination fee. This agreement was to expire on December 31, 2008.

Effective April 1, 2003, Biovail and Reliant amended certain terms of this agreement, such that Reliant was responsible for one-half of certain advertising and sales promotion costs incurred during 2003 related to the co-promoted products. Accordingly, Biovail's selling, general and administrative expenses in 2003 were recorded net of a reimbursement of \$25,000,000 received from Reliant. The amended terms also increased the tiered co-promotion fee payable to Reliant.

Effective December 31, 2003, Biovail and Reliant mutually agreed to terminate the co-promotion agreement (as amended). Consequently, Biovail recorded a charge of \$61,348,000 to extinguish its trailing royalty obligation to Reliant.

During the period covered by the co-promotion agreement (as amended), Biovail made loans to Reliant, which were repaid by Reliant coincident with the termination of this agreement (as described in note 10 Other Assets).

GSK

In October 2001, Biovail and GSK entered into an agreement for the development and license of Wellbutrin XL and the co-promotion of Wellbutrin SR®. Under the terms of this agreement, Biovail licensed Wellbutrin XL to GSK for sale and distribution in the United States. Biovail also granted GSK the option to elect to license Wellbutrin XL for sale and distribution on a worldwide basis, excluding Canada. Biovail and GSK collaborated to complete the development of Wellbutrin XL and to obtain FDA approval for this product. In addition, GSK and Biovail co-promoted GSK's Wellbutrin SR® in the United States during the period from January 1, 2002 to March 31, 2003. In consideration for the activities undertaken by Biovail under this agreement, GSK committed to pay Biovail up to \$61,500,000 in six quarterly increments. The first increment of \$11,500,000 was related to the development of Wellbutrin XL. During 2002, Biovail completed the development of Wellbutrin XL and recognized the first increment in research and development revenue. The five remaining quarterly increments, of up to \$10,000,000 each, related to the co-promotion of Wellbutrin SR® in the United States. The receipt of each of these increments was dependent on Biovail performing prescribed detailing activity related to the co-promotion of Wellbutrin SR®, and the amount was determined based on a percentage of net sales of Wellbutrin SR® in the United States during each quarter. Biovail received the full amount of these increments in each of the four quarters of 2002 and the first quarter of 2003.

GSK filed an NDA for Wellbutrin XL with the FDA in August 2002 and received FDA approval for this product in August 2003. GSK has elected to exercise its option to develop and market Wellbutrin XL in the European Union and in certain other key Western, Central and East European markets, as well as in Asia, Latin America, the Middle East, Africa and certain other emerging world markets.

Under the terms of this agreement, Biovail is the exclusive manufacturer and supplier of Wellbutrin XL to GSK on a worldwide basis. The sale prices for trade product shipped to GSK during each calendar year are determined based on a tiered percentage of GSK's net selling prices (after taking into consideration GSK's provisions for estimated discounts, returns, rebates and chargebacks). The sale prices for sample product shipped to GSK are fixed based on the terms of this agreement.

22. RESEARCH AND DEVELOPMENT COLLABORATIONS

In the ordinary course of business, the Company enters into research and development collaborations with third parties to provide formulation and other services for its products under development. These collaborations target the Company's therapeutic areas of focus cardiovascular (including Type II diabetes), pain management and central nervous system, and typically include formulation and product development services being rendered by the developer. The developer may utilize its own technology, and, in other cases, the Company will allow access to its technology for the formulation and development of the product(s). In some cases, the Company has an ownership interest or an option to take an ownership position in the developer. In no case is the Company responsible for any of the developers' third party liabilities, nor has the Company guaranteed any debts, nor is the Company required under any circumstances to exercise any of its options.

These third party developers are typically compensated on the basis of fees for service, milestone payments or royalty payments from the future sales of the products under development, or some combination of these bases. In addition, in the ordinary course of business, the Company may enter into research and development collaborations with third parties whereby the Company may provide contract research, formulation development and other services to those third parties. The Company is typically compensated on the basis of fees for service, milestone payments, royalties from future sales of the product(s) or some combination of these bases.

BNC-PHARMAPASS

In July 2003, Biovail and PPII formed BNC-PHARMAPASS to advance the development of carvedilol, tamsulosin and eprosartan products (as described in note 3 Acquisitions).

Flamel Technologies S.A. ("Flamel")

In February 2003, Biovail licensed from Flamel the rights to manufacture and market an oral solid controlled-release formulation of acyclovir, for the treatment of episodic and recurrent genital herpes infections, in the United States and Canada. Flamel will be

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 20-F

responsible for completing the development of this product. Biovail paid Flamel an up-front payment of \$500,000, and Biovail will pay Flamel up to \$6,500,000 on the achievement of certain developmental milestones, as well as royalties on any future sales of this product.

Depomed

In July 2002, Biovail licensed from Depomed the rights to manufacture and market Metformin GR in the United States and Canada. Depomed will be responsible for completing the clinical development program in support of this product. If Metformin GR is approved by the FDA, Biovail will pay Depomed a \$25,000,000 milestone fee, as well as royalties on any future sales of this product.

Merck

In May 2002, Biovail entered into an agreement with Merck to develop, license and supply a new dosage format of a Merck product under development. Utilizing CEFORM technology, Biovail and Merck will conduct the development program and, subject to approval by the FDA, Biovail will manufacture and supply this new dosage format to Merck for commercialization. Biovail is entitled to receive a milestone payment on regulatory approval of \$250,000, as well as royalties on any future sales of this new dosage format.

Ethypharm

In April 2002 (as amended in September 2003 and February 2004), Biovail licensed from Ethypharm the rights to market Tramadol FT and Tramadol/Acetaminophen FT, as well as four other products, in the United States, Canada and Mexico. Biovail will pay Ethypharm a milestone payment of \$1,000,000 if Tramadol FT is approved by the FDA, and a royalty on any future sales of Tramadol/Acetaminophen FT (as described in note 3 Acquisitions). Biovail will also pay up to \$45,000,000 in milestone payments on the first regulatory approval of the four other products within the United States, Canada or Mexico, as well as royalties on any future sales of these products. Biovail has also entered into a cross-license agreement with Ethypharm, whereby the two companies grant to each other non-exclusive licenses to use Biovail's CEFORM technology and Ethypharm's Flashtab technology, respectively, relating to the development of new rapid dissolve pharmaceutical products. Biovail has not made any milestone payments to Ethypharm.

Procyon Biopharma Inc. ("Procyon")

In January 2002 (as amended in January 2004), the Company licensed from Procyon the rights to manufacture and market Fibrostat in the United States. Fibrostat is a topical therapeutic for scar management. The Company will pay aggregate fees of approximately \$7,100,000 to Procyon for the development of Fibrostat, subject to the attainment of certain milestones. If Fibrostat is approved by the FDA, the Company will pay a licensing fee to Procyon of approximately \$3,900,000, as well as royalties on any future sales of Fibrostat. Biovail has not paid any fees to Procyon.

23. LEGAL PROCEEDINGS

From time to time, the Company becomes involved in various legal and administrative proceedings, which it considers to be in the ordinary course of business. These proceedings include product liability, intellectual property, antitrust, governmental investigations and related private litigation. There are also ordinary course employment related issues and other types of claims in which the Company routinely becomes involved but which individually and collectively are not material.

Intellectual property

RhoxalPharma Inc. ("RhoxalPharma") has filed an Abbreviated New Drug Submission ("ANDS") in Canada, seeking approval of a generic version of Tiazac®. The Company has two patents listed in the Patent Registry and has instituted legal proceedings that will prohibit the issuance of a Notice of Compliance to RhoxalPharma until said proceedings are concluded, or until the expiry of 24 months from the date of the Notice of Allegation, whichever is earlier.

Novopharm Limited ("Novopharm") has filed an ANDS in Canada, seeking approval of a generic version of Wellbutrin® SR 100 mg and 150 mg. The Company has instituted legal proceedings that will prohibit the issuance of a Notice of Compliance to Novopharm until these proceedings are concluded, or until the expiry of 24 months after the date of the Notice of Allegation, whichever is earlier.

Torpharm, Inc. ("Torpharm") has filed an Abbreviated New Drug Application ("ANDA") in the United States, seeking approval for a generic version of Cardizem® CD (120 mg, 180 mg, 240 mg and 300 mg). The Company has instituted legal proceedings pursuant to the Hatch-Waxman Act that preclude the FDA from granting approval to Torpharm until the earliest of 30 months after the filing of the legal suit, a court decision of non-infringement or patent invalidity or a court decision to abbreviate the 30-month stay.

Torpharm has filed an ANDA in the United States, seeking approval for a generic version of Tiazac® (120 mg, 180 mg, 240 mg, 300 mg and 360 mg). The Company has instituted legal proceedings pursuant to the Hatch-Waxman Act that preclude the FDA from granting approval to Torpharm until the earliest of 30 months after the filing of the legal suit, a final court decision of non-infringement or patent invalidity, or a court decision to abbreviate the 30-month stay.

Product liability

Biovail Pharmaceuticals, Inc. ("BPI") has been named in two Complaints alleging personal injuries arising from Plaintiffs' use of Dura-Vent, a product containing PPA and formerly marketed by BPI. The Company believes that these claims are without merit and, in the event these actions proceed further, they will be vigorously defended. These actions have been currently stayed pending the outcome of legal proceedings in a larger class of PPA actions. The Company nevertheless believes that these claims are without merit and, in the event these actions proceed further, they will be vigorously defended.

Antitrust

Several class action Complaints have been filed against the Company in which these Plaintiffs have alleged that Biovail has improperly impeded the approval of a generic form of Tiazac. The Company believes that the complaints are without merit and that the Company's actions were in accordance with its rights as contained in the Hatch-Waxman Amendments and the law. Moreover, the position of the Company is that it is not responsible for Andrx Corporation's ("Andrx") inability to receive timely final marketing approval for its generic Tiazac considering that the Andrx product did not receive FDA approval for a lengthy period following the removal of all legal or regulatory impediments by the Company.

The Company has filed its Motion for Summary Judgment seeking to dismiss the consolidated actions.

Several consumer class action suits have been commenced jointly against the Company, Elan and Teva relating to an agreement between the Company and Elan for the in-licensing of Adalat CC products from Elan. The agreement in question has since been dissolved as a result of a settlement agreement with the FTC. Biovail believes these suits are without merit since the delay in the marketing or out-licensing of the Company's Adalat CC product was due to manufacturing difficulties the Company encountered and not because of any improper activity on its part.

The Company has filed an extensive Motion for the summary dismissal of these actions. The Company believes that these claims are without merit and, in the event these actions proceed further, they will be vigorously defended.

The Company had received an informal enquiry from the FTC with respect to the Company's acquisition and listing of certain patents relating to its Teveten® and Teveten® HCT products. The FTC has confirmed that it is satisfied with the Company's responses and will not be pursuing further action on this matter.

Securities Class Actions

The Company has received notification that a number of Securities Class Action Complaints have been filed naming Biovail and certain officers. The Complaints allege the Defendants violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, and Rule 10b-5 promulgated thereunder. More specifically the Complaints allege that Biovail and certain of its officers and directors made materially false and misleading statements during certain specified periods of time.

The legal process will require an amended and consolidated Complaint to be filed. The Company will, thereupon, consider the appropriateness of filing a Motion for the summary dismissal of this action.

The Company believes that these claims are without merit and, in the event these actions proceed further, they will be vigorously defended.

Defamation and tort

On April 29, 2003, Jerry I. Treppel, a former analyst at Banc of America Securities, commenced an action naming as Defendants the Company and certain officers thereof, and against Michael Sitrick and Sitrick & Company, Inc. (in their capacities as consultants to the Company), in which the Plaintiff has alleged that he was defamed by the Defendants and that the Company's actions resulted in damages to him by way of lost employment and employment opportunities.

The Company has filed an extensive brief requesting the summary dismissal of this action. A decision of the Court in this regard is pending.

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 20-F

The Company believes that these claims are without merit and, in the event this action proceeds further, it will be vigorously defended.

Government investigations

The Company has received notification from the U.S. Attorney, District of Massachusetts, on behalf of the U.S. Office of the Inspector General ("OIG") of Health and Human Services that a preliminary administrative inquiry has been initiated into the Company's clinical experience and marketing programs related to Cardizem® LA. The Company is providing the OIG its full cooperation in this inquiry.

The Company has received notification from the SEC indicating that the SEC is conducting an informal inquiry relating to the Company's financial performance for the fiscal year 2003. The Company is providing to the SEC its full cooperation.

The Company has received requests for information from the Ontario Securities Commission ("OSC") as part of the OSC's continuous disclosure review of public companies. The Company is responding and providing all requested information to the OSC.

In addition, the Company has received notification that the OSC "is conducting a routine enquiry into the trading of Biovail Corporation" securities prior to the issuance of press releases on October 3, 2003, which provided guidance for the third quarter, and October 30, 2003, which reported the financial results for the third quarter. The Company is providing the OSC its full cooperation.

Arbitration

On March 1, 2004, Biovail Laboratories Incorporated ("BLI"), a wholly-owned subsidiary of the Company, began legal proceedings through arbitration against Teva Pharmaceuticals Curacao N.V. ("Teva Curacao").

These proceedings stem from perceived improprieties by Teva Curacao in calculating the net sales from a basket of generic products exclusively licensed to Teva Curacao, from which BLI and Teva Curacao are to calculate their respective financial entitlements. These perceived improprieties were detected through a formal audit conducted by an independent accounting firm.

The Company expects these proceedings to be completed within a year from their commencement.

The outcome of all legal proceedings the Company is involved in, including losses that may result therefrom, cannot be reasonably predicted or foreseen. Accordingly, no provisions for potential losses related to any of these proceedings have been accrued for in these consolidated financial statements.

24. CONTRACTUAL OBLIGATIONS

Operating lease commitments

The Company leases certain facilities, vehicles and equipment under operating leases. Lease payments were approximately \$7,800,000, \$5,000,000 and \$5,200,000 in 2003, 2002 and 2001, respectively.

Future minimum annual lease commitments under operating leases for the years ending December 31 are approximately as follows:

	\$
2004	6,400
2005	7,100
2006	4,900
2007	3,400
2008	2,800
Thereafter	13,600
Total minimum lease commitments	38,200

Contingent milestone payments

The Company may be required to make the following milestone payments under research and development collaborations with third parties. These payments are primarily contingent on receiving regulatory approval for the products under development and, consequently, do not have defined maturities.

	Third party collaborator	Amount \$
Tramadol FT, and four other products	Ethypharm	46,000
Metformin GR	Depomed	25,000
Athpharma products	Athpharma	24,200
Pharma Pass products	PPII	15,985
Colonic Delivery System products	PPII	10,000
Fibrostat	Procyon	7,100
Acyclovir	Flamel	6,500
		134,785

Purchase obligations

In connection with the acquisition of Ativan® and Isordil® (as described in note 3 – Acquisitions), Biovail will pay Wyeth a \$20,000,000 additional rights payment, increasing at 10% per annum, on the approval by the FDA of the first Ativan® line extension product that may be developed by Biovail.

In connection with the manufacture and supply of Vasotec® and Vaseretic®, Biovail is obligated to make semi-annual payments to Merck for minimum product quantities (regardless of the actual product supplied). The remaining payments are payable semi-annually, on April 1 and October 1 of each year, in the following gross annual amounts: 2004 \$4,794,000; 2005 \$3,810,000; and 2006 \$3,589,000.

25. RELATED PARTY TRANSACTIONS

In June 2001, the Company acquired a corporate aircraft from an entity controlled by Mr. Melnyk for cash consideration of \$10,475,000. The exchange amount was established based on comparable market prices for this aircraft at the time of acquisition.

In March 2001, the Company loaned \$600,000 to a former executive officer. This loan is secured by a charge on the former officer's personal residence. This loan does not bear interest until March 1, 2004, and thereafter bears interest at a rate equal to the Company's rate of borrowing. This loan is due on March 31, 2008.

26. SEGMENTED INFORMATION AND MAJOR CUSTOMERS

The Company operates in one operating segment – the development and commercialization of pharmaceutical products. Management assesses performance and makes resource decisions based on the consolidated results of operations of this operating segment. Substantially all of the operations of the Company are directly engaged in or support this operating segment. Other operations are not material and share many of the same economic and operating characteristics as pharmaceutical products and, accordingly, they are included with pharmaceutical products for purposes of segment reporting.

Geographic information

	Revenue ⁽¹⁾			Long-lived assets ⁽²⁾		
	2003 \$	2002 \$	2001 \$	2003 \$	2002 \$	2001 \$
Canada	124,800	62,848	44,705	99,914	75,872	44,139
United States and Puerto Rico	692,853	713,615	528,722	284,665	382,457	354,692
Barbados and other Caribbean		9,533	3,448	1,379,278	1,351,042	663,995
Other countries	6,069	2,029	6,388	28,539	27,340	1,249
	823,722	788,025	583,263	1,792,396	1,836,711	1,064,075

(1) Revenue is attributed to countries based on the location of the customer.

(2) Consists of property, plant and equipment, goodwill, intangible and other assets, net of depreciation and amortization. Property, plant and equipment are attributed to countries based on their physical location, goodwill is attributed to countries based on the location of the related acquired business, and intangible and other assets are attributed to countries based on ownership rights.

Major customers

The following table identifies external customers accounting for 10% or more of the Company's total revenue:

	Percentage of total revenue		
	2003 %	2002 %	2001 %
Customer A	6	12	16
Customer B	13	23	31
Customer C	17	11	9
Customer D	12	9	7
Customer E	11	6	5

27. COMPARATIVE FIGURES

Prior to 2003, the Company included foreign exchange gains or losses as a component of selling, general and administrative expenses. In 2003, the Company adopted the presentation of foreign exchange gains or losses as an individual line item below operating income. The reclassification of a foreign exchange gain of \$700,000 and a foreign exchange loss of \$1,072,000 in 2002 and 2001, respectively, to conform to the presentation adopted in 2003, did not change net income as previously reported in those years.

Certain other of the prior years' figures have been reclassified to conform to the presentation adopted in 2003.

28. SUBSEQUENT EVENTS**BNC-PHARMAPASS**

In January 2004, PPII further reduced its interest in BNC-PHARMAPASS through a withdrawal of cash from BNC-PHARMAPASS. In February 2004, Biovail acquired PPII's remaining interest in BNC-PHARMAPASS for \$5,000,000. Biovail and PPII also agreed to terminate the development of tamsulosin, and the intellectual property related to this product was returned to PPII. The increase in Biovail's share of the fair values of the two remaining products (carvedilol and eprosartan), together with the consideration paid to acquire PPII's remaining interest in BNC-PHARMAPASS, resulted in an additional \$8,640,000 capitalized to acquired research and development in the three months ended March 31, 2004.

Tramadol/Acetaminophen FT

In February 2004, Biovail acquired Tramadol/Acetaminophen FT from Ethypharm, and the parties agreed to amend certain agreements between them (as described in note 3 Acquisitions).

Revolving term credit facility

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 20-F

In March 2004, Biovail renewed its revolving term credit facility (as described in note 13 Long-Term Obligations).

F-89

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 20-F

Item 19. Exhibits

- 1.1 Amendment to By-Laws of the Company to change quorum requirements for meetings of shareholders of the Corporation, dated December 30, 1999⁽¹⁾
 - 1.2 Conforming Copy of Amended By-Laws of the Company effective December 30, 1999⁽¹⁾
 - 1.3 Articles of Amendment dated December 31, 1999 effecting a stock split and an increase in the authorized share capital of the Company⁽²⁾
 - 1.4 Articles of Amalgamation dated February 18, 2000 effecting a change in the name of the Company⁽²⁾
 - 1.5 Articles of Amalgamation of Biovail Corporation International⁽²⁾
 - 1.6 Articles of Amendment of Biovail Corporation International⁽²⁾
 - 1.7 Articles of Amalgamation of Biovail Corporation⁽²⁾
 - 1.8 By-law No. 1A of Biovail Corporation⁽²⁾
 - 2.1 Indenture, dated as of March 28, 2002, between Biovail Corporation, Computershare Trust Company, Inc., as U.S. trustee and Computershare Trust Company of Canada, as Canadian trustee⁽³⁾
 - 2.2 First Supplemental Indenture, dated as of March 28, 2002, between Biovail Corporation, Computershare Trust Company, Inc., as U.S. trustee and Computershare Trust Company of Canada, as Canadian trustee⁽⁴⁾
 - 8.1 Subsidiaries of Biovail Corporation (see Item 10.I of this report)
 - 10.a.1 Consent of Ernst & Young LLP
 - 12.1 Certification of the Chief Executive Officer pursuant to §302 of the Sarbanes-Oxley Act of 2002.
 - 12.2 Certification of the Chief Financial Officer pursuant to §302 of the Sarbanes-Oxley Act of 2002.
 - 13.1 Certificate of the Chairman of the Board and Chief Executive Officer of Biovail Corporation to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
 - 13.2 Certificate of the Senior Vice President and Chief Financial Officer of Biovail Corporation pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
 - 99.1 Schedule II Valuation and qualifying accounts
-

(1) Incorporated by reference to Registrant's Annual Report on Form 20-F for the fiscal year ended December 31, 1999, File No. 001-11145.

(2) Incorporated by reference to Registrant's Registration Statement on Form 8-A, filed with the SEC on March 17, 2000, File No. 001-14956.

(3) Incorporated by reference to Exhibit 1.1 on registrants report on Form 6-K dated May 21, 2002 submitted to the SEC on May 21, 2002, file #00114956.

(4) Incorporated by reference to Exhibit 1.1 on registrants report on Form 6-K dated May 21, 2002 submitted to the SEC on May 21, 2002, file #00114956.

SIGNATURES

The registrant hereby certifies that it meets all of the requirements for filing on Form 20-F and that it has duly caused and authorized the undersigned to sign this annual report on its behalf.

BIOVAIL CORPORATION

Date: May 14, 2004

By:

Brian H. Crombie
*Senior Vice President and
Chief Financial Officer*

III-2

EXHIBIT INDEX

- 1.1 Amendment to By-Laws of the Company to change quorum requirements for meetings of shareholders of the Corporation, dated December 30, 1999⁽¹⁾
- 1.2 Conforming Copy of Amended By-Laws of the Company effective December 30, 1999⁽¹⁾
- 1.3 Articles of Amendment dated December 31, 1999 effecting a stock split and an increase in the authorized share capital of the Company⁽²⁾
- 1.4 Articles of Amalgamation dated February 18, 2000 effecting a change in the name of the Company⁽²⁾
- 1.5 Articles of Amalgamation of Biovail Corporation International⁽²⁾
- 1.6 Articles of Amendment of Biovail Corporation International⁽²⁾
- 1.7 Articles of Amalgamation of Biovail Corporation⁽²⁾
- 1.8 By-Law No. A of Biovail Corporation⁽²⁾
- 2.1 Indenture, dated as of March 28, 2002, between Biovail Corporation, Computershare Trust Company, Inc., as U.S. trustee and Computershare Trust Company of Canada, as Canadian trustee⁽³⁾
- 2.2 First Supplemental Indenture, dated as of March 28, 2002, between Biovail Corporation, Computershare Trust Company, Inc., as U.S. trustee and Computershare Trust Company of Canada, as Canadian trustee⁽⁴⁾
- 8.1 Subsidiaries of Biovail Corporation (see Item 10.I of this report)
- 10.a.1 Consent of Ernst & Young LLP
- 12.1 Certification of the Chief Executive Officer pursuant to §302 of the Sarbanes-Oxley Act of 2002.
- 12.2 Certification of the Chief Financial Officer pursuant to §302 of the Sarbanes-Oxley Act of 2002.
- 13.1 Certificate of the Chairman of the Board and Chief Executive Officer of Biovail Corporation to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
- 13.2 Certificate of the Senior Vice President and Chief Financial Officer of Biovail Corporation pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
- 99.1 Schedule II Valuation and qualifying accounts

(1) Incorporated by reference to Registrant's Annual Report on Form 20-F for the fiscal year ended December 31, 1999, File No. 001-11145.

(2) Incorporated by reference to Registrant's Registration Statement on Form 8-A, filed with the SEC on March 17, 2000, File No. 001-14956.

(3) Incorporated by reference to Exhibit 1.1 on registrants report on Form 6-K dated May 21, 2002 submitted to the SEC on May 21, 2002, file #00114956.

(4) Incorporated by reference to Exhibit 1.1 on registrants report on Form 6-K dated May 21, 2002 submitted to the SEC on May 21, 2002, file #00114956.

QuickLinks

TABLE OF CONTENTS GENERAL INFORMATION PART 1

PART I

In accordance with U.S. GAAP (All dollar amounts are expressed in thousands of U.S. dollars, except number of shares and per share data)

In accordance with Canadian GAAP (All dollar amounts are expressed in thousands of U.S. dollars, except number of shares and per share data)

BIOVAIL CORPORATION MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS INDEX

SUMMARY COMPENSATION TABLE

Options Granted in Last Fiscal Year

AGGREGATE OPTIONS EXERCISED IN LAST FISCAL YEAR AND OPTION VALUES

PART II

PART III

INDEX TO FINANCIAL STATEMENTS

MANAGEMENT REPORT

AUDITORS' REPORT

Consolidated Balance Sheets

BIOVAIL CORPORATION CONSOLIDATED STATEMENTS OF INCOME (LOSS) In accordance with U.S. generally accepted accounting principles (All dollar amounts expressed in thousands of U.S. dollars, except per share data)

Consolidated Statements of Shareholders' Equity

BIOVAIL CORPORATION CONSOLIDATED STATEMENTS OF CASH FLOWS In accordance with U.S. generally accepted accounting principles (All dollar amounts expressed in thousands of U.S. dollars)

BIOVAIL CORPORATION NOTES TO CONSOLIDATED FINANCIAL STATEMENTS In accordance with U.S. generally accepted accounting principles (All tabular dollar amounts expressed in thousands of U.S. dollars, except per share data)

MANAGEMENT REPORT

AUDITORS' REPORT

BIOVAIL CORPORATION CONSOLIDATED BALANCE SHEETS In accordance with Canadian generally accepted accounting principles (All dollar amounts expressed in thousands of U.S. dollars)

BIOVAIL CORPORATION CONSOLIDATED STATEMENTS OF INCOME (LOSS) In accordance with Canadian generally accepted accounting principles (All dollar amounts expressed in thousands of U.S. dollars, except per share data)

BIOVAIL CORPORATION CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY In accordance with Canadian generally accepted accounting principles (All dollar amounts expressed in thousands of U.S. dollars)

BIOVAIL CORPORATION CONSOLIDATED STATEMENTS OF CASH FLOWS In accordance with Canadian generally accepted accounting principles (All dollar amounts expressed in thousands of U.S. dollars)

SIGNATURES

EXHIBIT INDEX